NDMA/CTFA Vaginal Douche Products Task Group

R. William Soller, Ph.D.
Senior Vice President and
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Presentation Outline

- Overview
- Clinical Perspective
- Epidemiologic Considerations
- Labeling and Research

Experts

- Suzanne Trupin, M.D., F.A.C.O.G.
  - Head & Clinical Professor
    Department of Obstetrics and Gynecology
    University of Illinois College of Medicine at Urbana-Champaign
    Partner, Women's Health Practice, Champaign, IL
- Michael J. Rosenberg, M.D., M.P.H.
  - Clinical Associate Professor of Epidemiology and Obstetrics and Gynecology, University of North Carolina
    President, Health Decisions Inc., Chapel Hill, NC
- Kenneth Jay Rothman, Dr.P.H., M.P.H., D.M.D.
  - Professor, Departments of Epidemiology and Medicine
    Boston University
    Senior Scientist, Epidemiology Resources Inc., Newton, MA

Market Demographics

- **> 1/3 American women douche**
  - 77% douche users are White, 20% Black
  - Over the past ten years, the percentage of women who say they have douched in the last 6 months has been constant.
  - Usually, douche users are under 50 years of age

- **1996:** 203 MM bottles of disposable douches sold
  - Over last ten years, douche unit sales have been constant

- **Product choices:**
  - 18%, only home prepared
  - 65%, only commercial
  - 17%, both home & commercial
  - @ 5% of the market = medicated douches

Based on company market research and published literature

Points to Consider

- Important to consider that:
  1 The outcomes of interest are consequences of sexual behavior.
  2 Difficulties in measuring of intimate behavior can be a source of residual confounding.
  3 Many women choose to douche and do so safely.
  4 Industry has already taken steps to amplify labeling and conduct research.

Presentation Outline

- Overview
- **Clinical Perspective**
- Epidemiologic Considerations
- Labeling and Research

Clinical Perspective

Suzanne Trupin, M.D., F.A.C.O.G.

Head and Clinical Professor
Department of Obstetrics and Gynecology
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Clinical Perspective

Suzanne Trupin, M.D., F.A.C.O.G.

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Partner, Women's Health Practice, Champaign, IL

Women's Health Practice Focus

***Primary Care**

***Accessible Care**

***At Risk Population**

Women's Health Practice

- Large community practice in an at risk population 50% 19-39 yo
- Detailed counseling and education
- Practice disease rate estimates
- Douching practices

Annual History and Physical Evaluation

- Full patient histories
- Lifestyle/Psychosocial
- STD Screening
- Obstetrical and Gynecological History
- Sexuality

Sexuality

- Orientation
- Function
- Risk Behaviors
- Contraception
- Lifetime Partners
- Current Partner
- Relationship Length
- Partner selection
- Barrier Protection

Physical Examination and Laboratory Examination

Chlamydia
+ GC - DNA probe test

- Breast exam/Pelvic exam
- Annual Pap Smears
- CT/GC Testing
- RPR/HbsAG/HIV
- Vaginal Wet Preps
- Urine Cultures

Contraception

- None or Inconsistent: 15-20 %
- Steroid Contraception: 40-50 %
- Condoms: 5 % primary
- IUDs, Norplants, TLs

WHP Vaginitis 1996

- Bacterial Vaginosis: 75%
- Trich: <5%
- Yeast: 20%

APPEARS THIS WAY
ON ORIGINAL

WHP Selected Disease Statistics 1996

■ Chlamydia:	5%
■ Gonorrhea	1%
■ PID	2-3%
■ EP	<1%
■ Colposcopies	5-6%

WHP Clinical Experience
Etiology of PID, EP and Infertility

- Numbers of Partners
- Early age at first intercourse
- Early age at first parous event
- Smoking
- Substance Abuse
- High Risk Partners
- **Unprotected Intercourse**

Summary

- 50-60% of Patient Population Douches
- PID/EP development is driven by sexual behavior
- Educate women and clinicians about how to prevent STDs
- Educate women and clinicians about safe douching practices

Epidemiologic Perspective

Michael J. Rosenberg, M.D., M.P.H.
Clinical Professor of Epidemiology and
Obstetrics and Gynecology
University of North Carolina
President, Health Decisions Inc., Chapel Hill, NC

Outcomes studied

- STD acquisition
- PID
- Ectopic pregnancy
- Infertility
- Cervical carcinoma

--All associated with STDs

Overview

All studies were retrospective, so:

- Involved questions regarding intimate behaviors, many going back long periods
- Difficult to assess validity or reliability of STD risk indices
- All case-control or cross-sectional, so impossible to assess magnitude of problem, if any

Overview

Literature generally suggests elevated ORs among women who douche, but associations are generally weak and inconsistent

- **Race, frequency, reasons for douching**
- **Little detail on how STD risk questions were asked or validated**
- **Fall in OR after adjustment indicates presence of confounding bias, but residual confounding, if any, impossible to assess**

--Collectively suggest presence of residual confounding bias

Characteristic	OR	Outcome	Author
Race			
Black	1.1	PID	Wolner-Hanssen
	2.6*	PID	Jossens
Frequency			
1-3x/mo	1.8	PID	Scholes
≥1x/wk	3.9*		
q few mo.	1.2	EP	Daling
1x/mo	1.5		
1x/wk	1.3		
Other			
Lack of contraception	7.6*	PID	Jossens
>1 recent sex partner	11.1*		
Douching not related to PID			

* Statistically significant

Conclusions

- Outcomes are recognized sequelae of STDs
- Presence of residual confounding bias
- Lack of assurance about reliability of measurement of STD risk

--All preclude any assessment regarding causality

Vaginal Douching and PID

Study design, dates, site	Sample Size, source (case/control or exposed/unexposed)	Main findings Odds Ratio (95% CI)*		Comments	Reference
Case-control, 1983-87, Seattle Washington	100 Emergency room + STD clinic/762 same	Race		Controlled for age, race, parity, education, smoking, age at first sex, sexual frequency, hx of chlamydia, gonorrhea, PID, contraceptive type	Wolner-Hanssen 1990
		White	3.5 (1.9-6.4)		
		Nonwhite, non-black	3.8 (1.0-15.1)		
		Black	1.1 (0.5-2.1)		
		Frequency			
		1-2x/month	1.6 (0.6-4.0)		
		3+x/month	3.4 (1.1-10.4)		
		Lifetime sex partners		Lifetime sex partners category is unadjusted	
		<10	3.5 (1.9-6.4)		
		11-25	2.4 (0.8-6.9)		
		≥ 26	1.8 (0.8-4.0)		
Case-control, 1984-85, Western Washington	131 HMO subscribers with first episode PID/ 294 with no PID	Douching Frequency		Controlled for age, race, marital status, gravidity, no. sex partners in past 12 months	Scholes 1993
		≥ 1x/week	3.9 (1.4-10.9)		
		1-3x/month	1.8 (1.0-3.4)		
		Past 3 months	2.1 (1.2-3.9)		
		Douching Reasons			
		Infection	7.9 (2.6-24.2)		
		After menses	1.3 (0.5-3.4)		
		Other reasons	1.6 (0.8-3.3)		
		Frequency (excluding reason infection)			
		≤ 3x/month	1.4 (0.7-2.7)		
		≥ 4x/month	3.0 (1.0-9.1)		
Case-control, 1981-89, San Francisco	453 with Chlamydia or Gonorrhea/ 136 with PID but no STD	Frequency (GC vs. CT PID)		Controlled for race, age, no. sex partners in past 30 days, hx PID, education, contraceptive use in past 30 days, gonorrhea hx	Jossens 1994
		past month	1.25 (1.07-1.46)		
		past week	1.23 (1.04-1.46)		
		Frequency (CT vs. Non-STD PID)			
		past month	0.37 (0.17-0.81)		
		past week	0.25 (0.08-0.80)		
		Black Race:STD vs Non-STD PID	2.56 (1.68-3.9)		
Case-control,1986-89, San Francisco	234 STD clinic/ 122 same	Risk Factors		Controlled for age, gravidity, age at first sex, gonorrhea, parity, education, sex with menses	Jossens 1996
		Parity > 0	4.4 (2.3-8.4)		
		>1 sex partner in previous 30 days	11.1 (4.3-28.5)		
		Sex during previous menses	5.2 (1.9 14.5)		
		Lack of contraception	7.6 (4.1-14.1)		
		Douching	Not Significant	Crude OR = 2.20	

* Risk in women who douched compared to women who did not, except as noted

PID = Pelvic Inflammatory Disease

Vaginal Douching and Cervical Cancer

Study design, dates, site	Sample Size, source (case/control or exposed/unexposed)	Main findings Odds Ratio (95% CI)*	Comments	Reference
Case-control, 1959-63, Buffalo, New York	285 Invasive, In Situ and Metatastic/1,620	Frequency ≥ 1x/week 1.69 (1.2-2.4) Duration ≥ 25 years 2.25 (1.6-3.2)	Adjusted for age only	Graham 1979
Case-control, 1980-81 Los Angeles County	200 Invasive/200	Frequency 1-4/month 1.5 (0.9-2.3) ≥ 5/month 3.4 (1.7-6.8)	Controlled for age, race, no. sex partners, language	Peters 1986
Case-control, 1982-84 Birmingham, Chicago Denver, Miami, and Philadelphia	418 Invasive/704	Frequency 1/month 0.85 (0.5-1.6) 5-8/month 1.39 (0.8-2.5) ≥ 9/month 1.30 (0.7-2.4)	Adjusted for age, race, age at first sex, no. partners, no. of births, cigarette history, OC use, prior nonspecific genital infection	Brinton 1987
Case-control, 1986-87, Colombia, Costa Rica, Mexico and Panama	759 Invasive/1,430	Frequency <1x/week 1.8 (1.0-3.3) 1-2x/week 1.1 (0.7-1.8) >2x/week 1.6 (1.0-2.4)	Adjusted for age, no. sex partners, age at first intercourse, presence of HPV, time since last Pap, no. pregnancies	Herrero 1990
Case-control, 1984-87 Utah	266 Invasive and In Situ/408	Frequency ≥4/mo 4.4 (1.9-10.0)	Adjusted for smoking, age, lifetime sex partners, church attendance, education	Slattery 1991
Case-control, 1984-87 Utah	266 Invasive and In Situ/408	Frequency < 1/month 1.0 (0.6-1.6) 1-2/month 1.2 (0.7-2.1) >4/month 4.7 (1.9-11.0)	Adjusted for age, no. lifetime sex partners, smoking, religious activity, education level	Gardner 1991

* Risk in women who douched compared to women who did not, except as noted

Vaginal Douching and Ectopic Pregnancy

Study design, dates, site	Sample Size, source (case/control or exposed/unexposed)	Main findings Odds Ratio (95% CI)*		Comments	Reference
Case-control, 1975-79, King County, Washington	155 Surgical ectopics/ 456 birth records	Frequency		Adjusted for race, condom use, smoking, gravidity, year of index pregnancy, use of Dalkon shield	Chow 1985
		Occasional	1.4 (0.9-2.2)		
		Weekly	2.0 (1.0-4.0)		
		Solution			
		Water	1.5 (0.4-5.3)		
		Noncommercial	1.2 (0.4-3.2)		
		Commercial	4.4 (1.6-12.7)		
Case-control, 1985-87, Los Angeles and San Francisco, California	306 Surgical ectopics/ 266 pregnancies	Douching	2.1 (1.3-3.5)	Adjusted for age at first intercourse, no. lifetime sex partners, past infertility, nulliparity, chlamydia	Chow 1990
Case-control, 1981-86, Western Washington	273 Hospitalized ectopics/ 726 HMO subscribers of childbearing age	Frequency		Adjusted for lifetime number sexual partners, age, race, gravidity, residence	Daling 1991
		Every few months	1.2 (0.8-1.8)		
		1x/month	1.5 (1.0-2.2)		
		1x/week	1.3 (0.8-2.2)		
		Solution			
		Water with or without vinegar or soda	1.3 (0.8-2.0)		
		Commercial	1.3 (0.9-2.0)		
		Chlamydial serology			
		Positive	3.6 (1.6-7.9)		
		Negative	0.9 (0.5-1.7)		
Case-control, 1986-87, Boston, Massachusetts	69 Surgical ectopics/ 101 prenatal patients	Frequency		Controlled for education, race, smoking, parity, history of PID, prior ectopic	Phillips 1992
		1+/month	0.8 (0.3-2.2)		
Case-control of black women, 1988-90, Atlanta, Georgia	197 Surgical ectopics/ 882 births, 237 abortions	Ever douched	3.8 (1.6-8.9)	Adjusted for age, parity, marital status, smoking, infertility, IUD use, prior STD, prior PID, no. partners	Kendrick 1995
		10+ years douching	6.1 (2.6-14.6)		

* Risk in women who douched compared to women who did not, except as noted

Vaginal Douching and Infertility

Study design, dates, site	Sample Size, source (case/control or exposed/unexposed)		Main findings Odds Ratio (95% CI)*		Comments	Reference
Case-control, 1980-83, King County, Washington	162 with primary tubal infertility/ 518 fertile women	Frequency ≤ 2x/year > 2x/year	Silent PID 1.8 (1.1-3.1) 1.6 (1.0-2.5)	O\ .t PID 3.0 (1.1-8.1) 2.2 (0.9-5.3)	Adjusted for age, cigarette smoking, no. prior sex partners	Mueller 1992
Case-control, King county, Washington	178 fertile douchers/ 662 fertile nondouchers	Douchers	2.9 (1.9-4.6)		Adjusted for cigarette smoking, frequency of sex, age, menses cycle length, OC use, history of ovarian cysts	Baird 1996

* Risk in women who douched compared to women who did not, except as noted
PID = Pelvic Inflammatory Disease

Vaginal Douching and STD acquisition

Study design, dates, site	Sample Size (case/ control or exposed/ unexposed), source	Main findings Odds Ratio (95% CI)*		Comments	Reference
Clinical Trial, 1948, Guatemala	6/6, prostitutes	Gonorrhea Syphilis	0.09 (0.01-0.70)*** 0.20 (0.01-4.17)***	Women washed external genitalia, douched with antibiotic solution Crossover design, 6 mo treated, 6 mo untreated; each woman had minimum of 3 contacts/day, 7 days/week	Funes 1952
Clinical Trial, ** Nevada	130/65, prostitutes	Gonorrhea	0.08 (0.02-0.37)***	Orthoidbenzoic acid douche; user group includes half women who preceded use of douches by 5 day tetracycline course	Edwards 1970
Clinical Trial, 1976-77, Bangkok	152/102, prostitutes	Gonorrhea	0.30 (0.20-0.40)***	No consideration of other risk factors, though number of partners thought to be equal in both groups; povidone-iodine douche used	Limsuwan 1978
Cross sectional, 1992-93, Indonesia	599 pregnant women, Public health clinic	Any STD Timing After sex Before and/or After sex	 1.8 (0.7-5.2) 2.6 (1.0-7.1)	Controlled for age, education, hx STD; all women douched before or after sex; outcome included gonorrhea, chlamydia, syphilis, trichomoniasis, HSV-2; douches included water, water + soap, betel or commercial agent	Joesoef 1996
Cross Sectional, 1984-86, Seattle/King County	50 BV/25 yeast/7 trich	Reason: Cleanliness Outcome: Bacterial Vaginosis Yeast Vaginitis Trichomoniasis	 2.1 (1.0-4.3) 1.8 (0.5-6.3) 1.0 (0.1-11.0)	Two year follow-up study. Adjusted for age, race, barrier methods of contraception, antibiotic use, hx of Bacterial Vaginosis, yeast vaginitis or trichomoniasis.	Hawes 1996

* Risk in women who douched compared to women who did not, except as noted
** Denotes information not specified
*** Data recalculated from published information

Epidemiologic Perspective

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Senior Scientist, Epidemiology Resources Inc.
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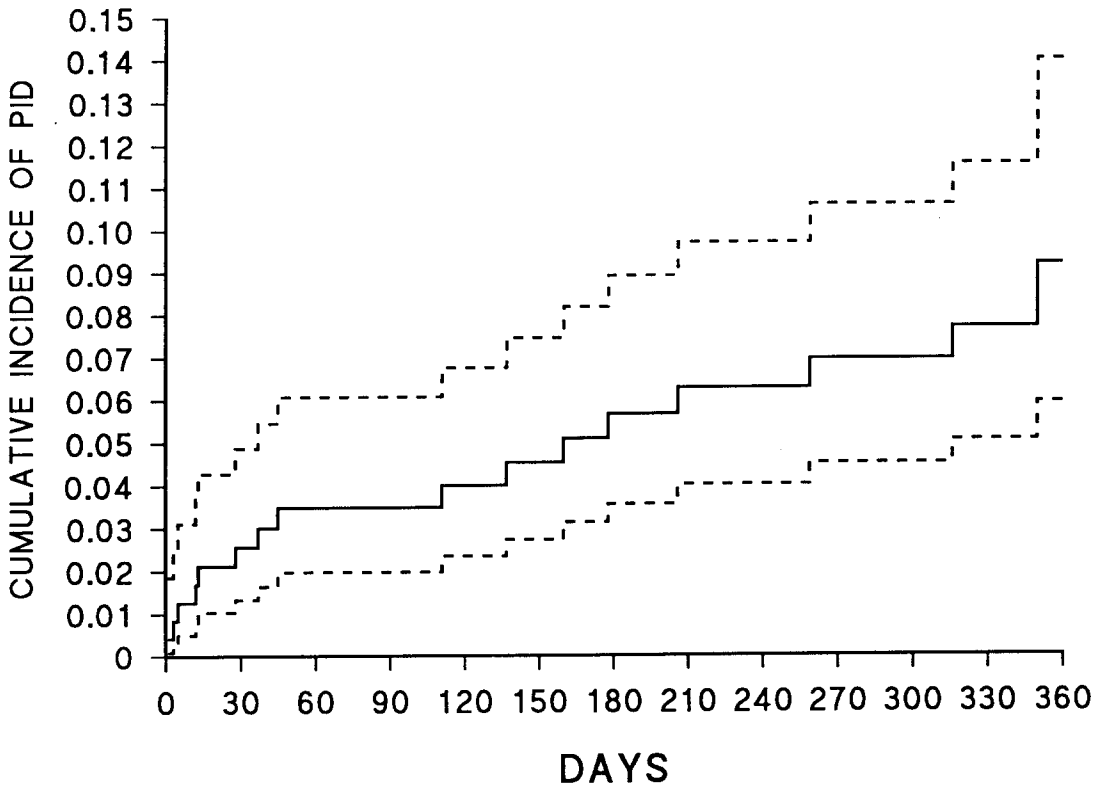
Epidemiology of PID

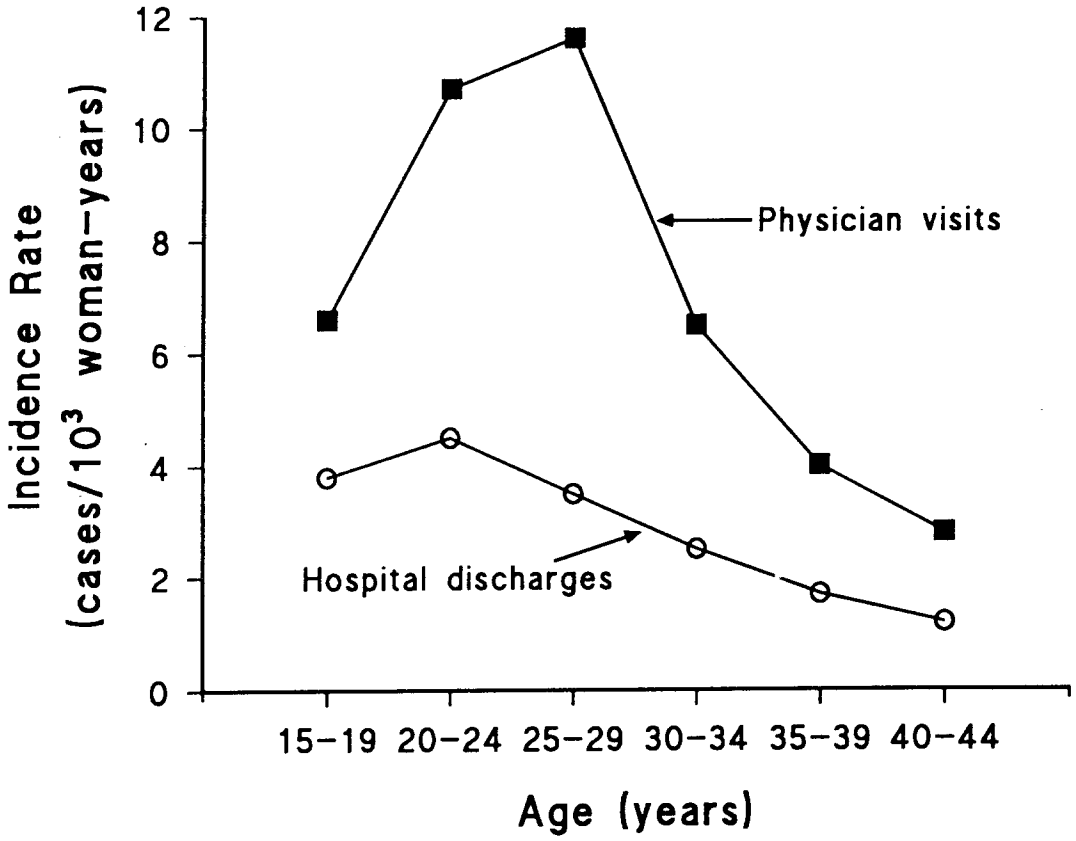
1. Demographics
   - Age
   - Race
   - Marital Status

2. Causal Theories
   - Cigarette smoking
   - STDs
   - Sexual behavior
   - Contraceptives
   - Douching

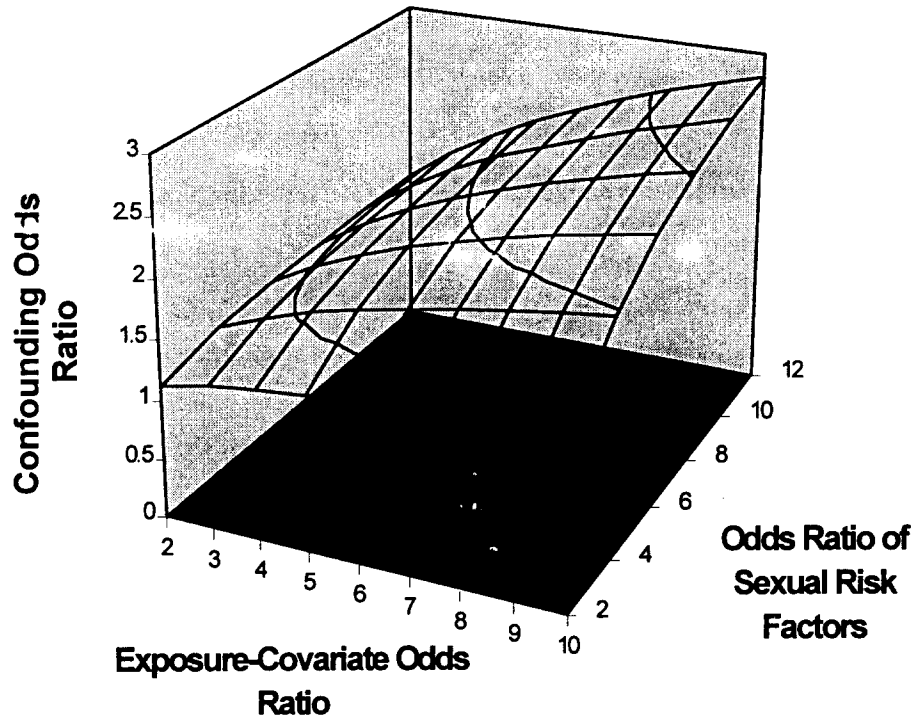
Cumulative Incidence of PID for Women treated for Gonorrhea and Chlamydia, with 90% Confidence Intervals



Age-specific Incidence Rates of PID



Sensitivity Analysis Showing the Magnitude of Potential Confounding by Sexual Risk Factors



Labeling and Research

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology
Nonprescription Drug Manufacturers Association

Labeling & Research

- Regulatory perspective
- Ongoing research
  - An overview of the prospective study
- Voluntary labeling
  - Current elements of labeling

*"Cleansing for Cosmetic Purposes" **

- "Transient cleansing effects"
- "Deodorizing"
- "Mechanical flushing"
- "Removes vaginal discharge"

"The agency has no objection to the continued availability of vaginal products bearing labeling claims related to <u>cleansing for cosmetic purposes</u>."

* (Terms/sentence in quotation marks are FDA's stated elaboration of the phrase, "cleansing for cosmetic purposes." See *Federal Register* 59: February 3, 1994.)

Ongoing Research

- Overview
  - An evaluation of feminine hygiene practices and their relation to PID
  - Independent and experienced investigators, coordinating investigator and advisory panel
  - Large prospective study: 3000 women

Ongoing Research

- Study population:
  - Women 18-34 years of age with a history of douching > 1/month and prior gynecologic bacterial infection treated with oral antibiotics
- Randomized Groups:
  A. Disposable douche (vinegar and water)
  B. Unscented soft cloth towelettes (external wipes)

*Current Elements of Labeling**

- **Warnings against use:**
  - for pregnancy prevention
  - during pregnancy
  - breast feeding (PVP-I)
  - self-treatment of STD or PID
- **Warnings to stop use:**
  - for emergent or persistent symptoms associated with product use
- **Warnings to stop use and see a doctor:**
  - for present or emergent symptoms of PID and STD
- **Directions:**
  - gentle insertion and use
  - non-occlusive application
  - frequency of use

*Not verbatim label text.

Current Elements of Labeling Educational Aspects: PID & STDs

- **Awareness** that an association has been reported
- **Most common symptoms** of PID:
  - pain or tenderness in the lower part of the abdomen and pelvis
  - vaginal discharge/ bleeding
  - nausea or fever
- **Similarity of STD symptoms** with those of PID, along with frequent urination, genital sores or ulcers.
- **Warning against use** of douches for self treatment of any STDs or PID.
- An **advisory to stop use** and **see a doctor**

Summary

- Clinical and epidemiologic perspectives
- Current elements of labeling
- Ongoing research

Mark G. Martens, M.D., F.A.G.O.C.

Chairman, Department of Obstetrics and Gynecology

Hennepin County Medical Center

Professor and Vice Chairman, Department of Obstetrics and Gynecology

University of Minnesota School of Medicine

to the

Food and Drug Administration Nonprescription Drugs Advisory Committee Panel Meeting

April 15, 1997

STATEMENT OF MARK MARTENS, M.D., FACOG

I. INTRODUCTION

My name is Mark Martens, M.D. I am a Professor and Vice Chairman of the Department of Obstetrics and Gynecology at the University of Minnesota School of Medicine in Minneapolis. I am also the Chairman of the OB/GYN Department at the Hennepin County Medical Center. My undergraduate training was at Kenyon College (BA, Biology). I performed graduate degree work in microbiology at Northwestern, prior to attending medical school at George Washington University. I served my internship and residency in OB/GYN at Hartford Hospital, followed by an OB/GYN Infectious Disease Fellowship at Baylor College of Medicine.

II. MY REASONS FOR CONTRIBUTING TO THIS MEETING

A. Request from The Weinberg Group

B. Recommendations by colleagues

C. Current practice - -Director of Minneapolis Vulvovaginitis Center; collaboration of Clinical Physician/Practitioners and OB-GYN Microbiology Laboratory

D. Previous Research

1) Vaginitis, Antibiotic effects in Vagina and Pelvic Infection Including PID at Baylor College of Medicine, University of Texas and Emory University

III. CURRENT DISCUSSION -- ASSESSING ASSOCIATION OF DOUCHING TO DISEASE

A. PID

1. There are 3 theories proposed as Biological Mechanisms

a) Physical Propulsion of Bacteria:

While implication of this method appeared quite reasonable in the 1980's and early 1990's, recent data has brought this theory into question.

1) Abner Korn and colleague's work on presence of pathogenic bacteria in the lower uterus without dependence of douching in patients with Bacteria Vaginosis (BV). This presence of bacteria above the cervix was not related to PID, although this was not a proposed outcome of the study.

2) McGregor's recent visual demonstration of rapid and massive movement of fluid (dye) into the upper genital tract and into the fallopian tube in minutes in non-pregnant women without douching is incompatible with the propulsion theory. Bacteria would be present in the upper genital tract of all women due to natural contractions/propulsion as described by Dr. Eshenbach earlier today in Dr. McGregor's current data.

b) Washing/Dissolution of Protective Cervical Mucous Theory

1) Glynn's earlier data demonstrating only alkaline douches were mucolytic.[1,2]

2) Monif and Osborne's data on positive effect of douching (i.e., using antibacterial effects of douching to replace systemic antibiotic use for prophylaxis of pelvic surgical procedures). It did not work because mucous was not affected (92% reduction in vaginal bacteria, but only 8%

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[1] Glynn, R. 1963. Daily douching: Effect on vaginal mucosa. Obstet. Gynecol. 22:640-642.

[2] Glynn, R. 1962. Vaginal pH and the effect on douching. Obstet. Gynecol. 20:369-372.

reduction in cervical mucous bacteria cultures).[3,4]

c) Alteration of Flora - Lactobaci[illegible]:

1) Monif -- Antibacterial effect of douching on lactobacillus occurs at 10 minutes of douching, but no statistical difference at 30 minutes.[5]

2) Onderdonk and colleagues excellent study demonstrating similar reduction at 10 minutes, but statistically return to normal at 4 hours (the next culturing interval).[6]

3) Hillier -- Even with antibiotic creams or gels utilized once to twice daily for up to 5-7 days, normal return of most flora including Lactobacilli occur at 1-4 weeks.

CONCLUSION: None of the 3 theories are supported by compelling data.

IV. EPIDEMIOLOGY

Strengths and weaknesses of current literature have been and will certainly be discussed by others. There have been no large prospective studies. In retrospective studies, it is very difficult to ascertain cause and effect, because some of the major reasons for douching are associated

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[3] Monif, G.R.G., Thompson, J.L., Stephens, H.D. and Baer, H. 1980. Quantitative and qualitative effects of povidone-iodine liquid and gel on the aerobic and anaerobic flora for the female genital tract. Am. J. Obstet. Gynecol. 137:432-438.

[4] Osborne, N.G., and Wright, R.C. 1977. Effect of preoperative scrub on the bacterial flora of the endocervix and vagina. Obstet. Gynecol. 50:148.

[5] Monif, G.R.G., Thompson, J.L., Stephens, H.D. and Baer, H. 1980. Quantitative and qualitative effects of povidone-iodine liquid and gel on the aerobic and anaerobic flora for the female genital tract. Am. J. Obstet. Gynecol. 137:432-438.

[6] Onderdonk, A.B., Delaney, M.L., Hinkson, P.L. and DuBois, A.M. 1992. Quantitative and qualitative effects of douche preparations on vaginal microflora. Obstet. Gynecol. 80:333-338.

with factors known to be related to PID. Studies have ascertained that the main reasons for douching are preventative, personal hygiene and perception of infection.

Even as a clinician trying to define risk factors, there are biases even in adjusted/multivariate analyses.

Epidemiology studies can best be summarized by a classic paper published in the Journal of the American Medical Association by one of the most experienced PID epidemiologist and colleagues.[7]

In order not to go over my allotted time, the association of douching with ectopic pregnancy and cervical cancer are less compelling.

VI. CONCLUSION

Despite my multiple duties as Chairman, 90% of my clinical time is spent at the Vulvovaginitis Center. My clinical philosophy is similar to many of my colleagues, and that is that vaginal floral balance is one of the most important factors in preventing serious upper genital tract disease. Systemic antibiotic use is a significant cause of many of these imbalances. Therefore I strive to avoid the use of vaginal ecosystem disruption antibiotic usage. I rely very heavily on the use of both acidifying and alkalizing douches to try to return the vaginal ecosystem to balance.

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[7] Washington, A.E., Aral, S.O., Wolner-Hanssen, P., Grimes, D.A., and Holmes, K.K. 1991. Assessing risk for pelvic inflammatory disease and its sequelae. JAMA 266:2581.

A recent analysis of my patients demonstrate a reliance of douching as first time therapy in 80% of my patients. The douching regimens are used in conjunction with concomitant regimens to either help normalize a lactobacillus alteration until the time that direct lactobacillus and floral normalization products are available, douching is one of the most important components of this process. In Europe, lactobacilli in the form of douches is a common method to treat vaginitis.

My final conclusions are:

1) It is obvious and repeatedly concluded by other scientists that research is necessary to study both the potential positive effects of douching and the potentially negative effects which may occur if douching is inappropriately over used or misused. The data has demonstrated that short term use does not produce long-term detrimental effects and at one time was demonstrated beneficial in certain indications, hence its previous FDA approval.

2) It is also evident that increased patient education is imperative to prevent inappropriate off-label or prolonged usage. I believe the situation is similar to the well documented detrimental effects of the misuse of another over-the-counter product (OTC antifungals). The use of these products have been demonstrated to be inappropriately utilized in over 50% of women, many of whom have more serious deficiencies such as BV or STDs. The answer to the antifungal abuse is not removal from the market, but greater patient education.

PonJola Coney, M.D., FACOG

Professor and Chair, Department of Obstetrics and Gynecology

Southern Illinois University School of Medicine

to the

Food and Drug Administration Nonprescription Drugs Advisory Committee Panel Meeting

April 15, 1997

STATEMENT OF PONJOLA CONEY, M.D., FACOG

My name is PonJola Coney, M.D. I am a Professor and Chair of the Department of Obstetrics and Gynecology at the Southern Illinois University School of Medicine.

I was asked by the Purdue-Frederick Company to attend this hearing to express my views about the safety and efficacy of douches in general, and about douches containing povidone iodine.

The issues that I will address in my remarks today are summarized as follows:

1. Despite the prevalence of douching by women, in my nearly 20 years of medical practice, I have never seen a woman who I felt was harmed by douching.

2. As a clinician, I am convinced of the importance of evidence-based medicine. I have seen no clinically relevant evidence that douching results in increased infection, cancer, or infertility.

3. I see three benefits of douching: It is a culturally mediated personal hygiene practice that makes some women feel better or cleaner, despite our belief that it is medically unnecessary. It can be used to treat minor vaginal lesions, and in my infertility practice, I require povidone iodine douches as an antiseptic step before egg harvesting. This protocol has been remarkably effective in infection prevention and control. After 13 years of using this protocol, I have not had one symptom or complaint that would suggest infection in this group of patients.

I will now elaborate on these three points.

1. The incidence of douching is high, but it has not been demonstrated that douching is harmful.

Women douche a lot. Aral et al. 1988 report that in a national sample, 37 percent of women reported douching. They also reported that the practice is strongly associated with race, with two-thirds of Black women, but only one-third of white women using douche. My professional experience is the same. While we know of no real need to douche unless instructed by a physician, the fact remains that many women do so. They have told me that they douche because it is cleansing, and an important part of their personal hygiene. It appears to be a culturally-mediated practice, handed down by mothers to daughters. I have never seen a patient for whom I felt that douching was harmful.

Douching is not an issue of concern in my practice of medicine. I do not even inquire about douching while taking a medical history, nor do I teach it to my residents. My specialty in infertility treatment leads me to see many patients with reproductive problems, including ectopic pregnancy, but there is no relationship between these

problems and a history of douching. If a patient asks about whether or not to douche, I tell them that there is no medical reason for them to douche, and I am not aware of any harm in doing so. It is a matter of personal choice. At this time, there is not enough evidence, to limit this choice.

2. **The assertions that douching leads to infection are not supported by fact.**

As a clinician, I cannot support the assertion that douching has a role in vaginal or other reproductive tract infections based on the literature I have seen.

First, I will note that the cervix is an extremely competent organ, and it is more than capable of resisting the passage of pathogens that are allegedly propelled by douching.

Second, I think that doctors will agree that the infections and irritations that we treat are the result of sexual activity, and sexual transmission. Douching is not the source of the infections.

Third, douching does not mask significant infections by organisms such as *Chlamydia, Gardnerella, or Neisseria*, because it will not stop the symptoms, and women will come in to the office for treatment. If we thought that douching were masking symptoms and delaying treatment, then we would have a major problem of indolent disease.

The population that douches happens to be the same population with the highest rates of sexually transmitted diseases, with the least access to care, and with the highest morbidity for ectopic pregnancy and cervical cancer. It is my understanding that this agency and other federal agencies have a mandate to encourage the practice of evidence-based medicine. But there is not enough evidence at this time to counsel these patients that douching, rather than sexual activity, and access to treatment has an impact on their health.

3. **There are in fact, medical benefits from douching in general, and from the use of povidone iodine douches specifically.**

A point that I have already made, is that douching has long been accepted as a hygiene practice in some cultures. While it may be medically unnecessary, for some women it is as much a part of personal care as tooth brushing or hair washing. If we think of how we feel better, cleaner, and more attractive with these activities, then we may better understand the cosmetic benefits a large number of women feel that they achieve with douching.

A second benefit is in the treatment of vaginal lesions. I occasionally prescribe povidone iodine douches to treat local lesions, or for treatment of discharge and irritation when infection is not evident.

Finally, I would like to tell you that I instruct every patient who will undergo egg harvesting in my infertility clinic to self administer a povidone-iodine douche the night before the procedure. This protocol has been a simple and effective means of reducing microbial contamination. I have never had a problem with this protocol. With over 1500 egg harvests, there has never been an instance of ectopic pregnancy or "rebound" infection that I would attribute to the douche regimen.

APPEARS THIS WAY
ON ORIGINAL

Trudy Svala Berkowitz, Ph.D.

Professor- Departments of Obstetrics, Gynecology and Reproductive Science, and Community Medicine

Mount Sinai School of Medicine

to the

Food and Drug Administration Nonprescription Drugs Advisory Committee Panel Meeting

April 15, 1997

Trudy Svala Berkowitz, Ph.D.
April 15, 1997

SLIDE 1

My name is Trudy Svala Berkowitz. I am a Professor at Mount Sinai School of Medicine. I have spent the past 20 years working in reproductive epidemiology. I have been asked by the Purdue-Fredrick Company to independently review the epidemiologic data on douching and to provide my conclusions.

Although epidemiologic studies have shown an association between vaginal douching and PID and ectopic pregnancy, the existing data can not be used to establish a casual association. Following are the most important limitations of the published studies.

SLIDE 2

- Case control differences

  Substantial case-control differences exist in all the studies, namely the cases are more likely to be poor, to have initial sexual intercourse at a younger age, and to have had a history of more sexual partners than the controls. Many of the studies have not controlled for these or other so-called potentially confounding factors.

- STDs

  Sexually transmitted diseases are the major cause of PID and indirectly of ectopic pregnancies. All of the epidemiologic studies related to douching have been case-control or cross-sectional investigations, which can not sort out the temporal sequence between douching and the onset of STDs. It is essentially the problem of the chicken and the egg -- which came first? Furthermore, data show that STD use is under reported by about 50%.

- Male Partner

  We do know that the number of sex partners of the man represents a very important vector for STD. It has also been shown that douchers are more likely to have sexual partners who had other sexual partners. Yet, none of the epidemiologic studies on douching and PID and ectopic pregnancy have asked about the number and type of partners of the man.

- Douche Users

  It is well established that douche users come from populations already at risk for PID or ectopic pregnancy, notably they are poor and have a history of several sexual partners.

  Because of the difficulty of controlling for the substantial case-control differences, the inability of case-control and cross-sectional studies to determine the temporal relationship between STD and douching, particularly when the STDs are asymptomatic, and the absence of information on the male partner's partners, we simply do not have the data to show that douching causes PID, ectopic pregnancy, or cervical cancer.

SLIDE 3

Weight of the Evidence

Epidemiologic Data

- When epidemiologists try to distinguish a casual relationship from a statistical association, they typically assess the consistency of the results, the strength of the association, whether there is a dose-response relationship, whether the findings remain after adjustment for confounding variables, and whether there is a biological basis for the associations.

- First, it should be noted that there are only 2 individual studies specifically founded on PID, 4 on ectopic pregnancies, and 1 on cervical cancer.

- The findings in those as well as more general studies of risk factors of PID, ectopic pregnancy, and cervical cancer are not consistent. Some show a dose-response relationship, others do not. Some studies show a high relative risk, most do not, and adjustment for confounding variables is far from complete.

Clinical Data

- There are no published case reports of PID or ectopic pregnancy following douching.

Animal Data

- Non-existent.

Mechanistic Probability

- No scientifically documented mechanism has been reported.

As a result, I can not conclude that there is a casual association between douching and PID, ectopic pregnancy, or cervical cancer.

Carol J. Rowland Hogue, Ph.D., M.P.H.

Terry Professor of Maternal and Child Health and Professor of Epidemiology,
Rollins School of Public Health

Emory University

to the

Food and Drug Administration Nonprescription Drugs Advisory Committee
Panel Meeting

April 15, 1997

My name is Carol Hogue. I am a reproductive epidemiologist with more than 25 years' experience in methodologic and substantive studies of pregnancy outcome. I have been engaged by the Purdue-Frederick Company to examine the literature and provide my assessment to this committee.

SLIDE 1

Dr. Berkowitz (has provided) (will provide) an overview of the epidemiologic evidence on vaginal douching and illness. I am going to focus on the relationship of douching to sexually transmitted diseases (STDs). STDs are causally linked with PID, ectopic pregnancy, and cervical cancer in case-control studies. However, it has been estimated that as much as 50 percent of STDs are under-reported in such studies. Under-reporting occurs even if laboratory and surgical tests are performed. In the absence of laboratory confirmation, the woman's ability and willingness to recall STDs becomes an additional factor for under-reporting. Even in a high risk population in which virtually all women may report a history of STDs, under-reporting of severity of disease is likely to occur.

Under-reporting of STDs is an important consideration for examining the role of douching and STD-related diseases, because women's reports of douching are related to their history of STDs. That is, women with vaginal infections report greater use of douching than women without such infections. Also, women who are at greater risk of STDs because of their sexual practices douche more than women who are at lesser risk of STDs.

SLIDE 2

Non-differential misclassification bias occurs when individuals are misclassified with respect to the risk factor, irrespective of their disease status. Assuming that STDs are non-differentially under-reported in a case-control study, the result is to under estimate the relative risk of STDs for that disease. That is illustrated on this slide, with a hypothetical example based on the literature. The assumptions for this example are listed in your Handout #1. With a 50% non-differential misclassification bias, the observed odds ratio of 2.7 is much less than the true relative risk of 10.0.

In this example, 90% of women with STDs douche, but only 60% of women with no STDs douche. Merely because of this association of STDs and douching, the crude odds ratio for douching is 2.3 when the true odds ratio is 1.0.

SLIDE 3

In the group of women who have been correctly classified with STDs, the true odds ratio for douching of 1.0 is reported. It is in the group of women without STDs that the spurious elevation of 2.5 for the odds ratio for douching occurs.

SLIDE 4

With this example as an illustration, we can conclude the following: given the elevated risk of STDs for STD-related diseases; the under-reporting of STDs in case-control studies; and the observed association of STDs with douching -- case-control studies of PID, ectopic pregnancy, or cervical cancer cannot reliably assess the risk of douching among women classified as free from STDs. Among women with STDs, it is possible to circumvent non-differential misclassification bias to obtain a correct estimate of the association of douching with those diseases.

SLIDE 5

However, other methodological issues then come into play. As others have noted, douching may reduce the risk of infection among women exposed to STDs, particularly if they douche with medicated douches such as povidone-iodine solutions. An assessment of the complete role of douching in increasing or decreasing the risk of diseases caused by STDs must include the protective factor of STD prevention as well as the potential effect modification among women who are infected with STDs despite the fact that they douche. This complex relationship cannot be addressed in case-control studies limited to women with STDs.

Temporality is a separate, and very important, consideration. Several have suggested that since douching tends to be a life-long practice, it would precede infection with STDs. This cannot be assumed. The woman can be infected with an STD with her first experience of intercourse.

Thus, in case-control studies the investigator cannot determine which came first, STDs or douching.

SLIDE 6

This inability to determine temporality renders case-control studies incapable of separating causal from non-causal associations between douching and STD-related diseases. This example illustrates that a very similar odds ratio for douching can be found under very different conditions. In the first situation, douching increases the risk of STD-related disease by a factor of 3. In the second situation, douching is not causally associated with STD-related disease except through its association with the severity of STDs among women with STDs. Assumptions are listed on Handout #2. Again, the estimated odds ratio is about 3, but this is entirely adventitious, as the true relative risk for douching in the second situation is 1.0.

SLIDE 7

Because of considerations of the complex relationship between douching and STDs, including the inability of retrospective studies to determine temporality, we can conclude that causality cannot be determined from case-control studies of women with STDs.

In summary, case-control studies over-estimate the role of douching among women classified as being free of STDs and cannot be used to estimate the independent role of douching among women with STDs.

HANDOUT 1:
Carol J. Rowland Hogue, Ph.D.
April 15, 1997

ESTIMATING THE EFFECT OF NON-DIFFERENTIAL MISCLASSIFICATION ON RELATIVE RISK OF ECTOPIC PREGNANCY (EP) AND DOUCHING

Parameters estimated from the literature:

Prevalence of STD	50%
Misclassification of STD	50%
Douching among women without STD	60%
Douching among women with STD	90%
Risk of ectopic pregnancy among women with STD	10%
Risk of ectopic pregnancy among women without STD	1%

In a closed population of 1,000 pregnant women with 55 cases of ectopic pregnancy:

True relative risk (RR) of ectopic pregnancy:	
For women with STD, compared to women without STD	10.0
Observed odds ratio estimating this risk	*2.7*
For women who douche, compared to women who do not	1.0
Observed odds ratio estimating this risk	*2.3*
Among women correctly classified with STD, the estimated odds ratio for douching	1.0
Among women classified without STD (including misclassified who have STDs), the estimated odds ratio for douching	*2.5*

CONCLUSION:

Given:

- The risk of STDs for PID, EP, and cervical cancer
- The under-reporting of STDs in case-control studies
- The association of STDs and douching

CASE-CONTROL STUDIES OF PID, EP, OR CERVICAL CANCER CANNOT RELIABLY ASSESS THE RISK OF DOUCHING AMONG WOMEN CLASSIFIED AS FREE FROM STDs.

HANDOUT 2:
Carol J. Rowland Hogue, Ph.D.
April 15, 1997

ESTIMATING THE EFFECT ON RISK OF ECTOPIC PREGNANCY (EP) FROM DOUCHING IN RESPONSE TO FREQUENT STDs

Scenario A: *Douching increases the risk of EP among women with STDs*

Parameters estimated from the literature:

Prevalence of STD	50%
Misclassification of STD	50% (not a problem for this study)
Douching among women without STD	60% (not included in the analysis)
Douching among women with STD	90%
Risk of EP among women with STD	10%
Risk of EP among women with STD who douche	10.7%
Risk of EP among women with STD who do not douche	3.6%

In a closed population of 1,000 pregnant women with 55 cases of ectopic pregnancy:

True relative risk of douching	3.0
Estimated odds ratio	*3.2*

Scenario B: *Douching does not cause EP but is secondary to STDs, in that women with more severe STDs both douche more and are at increased risk of EP.*

Parameters estimated from the literature:

Prevalence of STD	50%
Misclassification of STD	50% (not a problem for this study)
Douching among women without STD	60% (not included in the analysis)
Douching among women with STD	90%
Among 1/3 of women with many recurrent infections, douching	100%
Among 1/3 of women with some recurrent infections, douching	90%
Among 1/3 of women with only one infection, douching	80%
Risk of EP among women with STD	10%
Among 1/3 of women with many recurrent infections, risk	15%
Among 1/3 of women with some recurrent infections, risk	10%
Among 1/3 of women with only one infection, risk	5%

In a closed population of 1,000 pregnant women:

True relative risk of douching	1.0
Estimated odds ratio	*3.5*

CONCLUSION:

CAUSALITY CANNOT BE DETERMINED WITH CASE-CONTROL STUDIES OF WOMEN WITH STDs.

Richard J. Stock, Jr., M.D., M.P.H.

CAPT, USN Naval Medical Center Portsmouth, Virginia

Associate Clinical Professor, Eastern Virginia Medical School

to the

Food and Drug Administration Nonprescription Drugs Advisory Committee Panel Meeting

April 15, 1997

Treatment of Vaginitis - 1960's

- If the patient douches
  - Tell her to stop
- If the patient doesn't douche
  - Tell her to douche
- But - Who douches? When? Why? How? Is it detrimental?

Potential Problems with Vaginal Douching

- Alter vaginal flora
  - Increase in yeast infections
  - Increase susceptibility of infection with STDs - PID
- Retrograde flow through uterus, tubes - PID / ectopic

Inherent Problems:

- Vaginal infection:
  - Self reported / wet smear / cultures
- PID - Clinical diagnosis
  - Laparoscopic confirmation 65 - 80 %
  - Culture confirmation 77 % / 50 %
- Ectopic pregnancy - ? Real change in incidence ?
  - Determination of numerator / Makinen - Finland
- What about Europe ? - No douching

25 years of interest and examination

Year	#	Incidence	Weekly	Volume
1970	1600	57%	47%	58% (1000cc)
1975	226	47%		
1988	60	43%	23%	60% (180cc)
1992	496	55%	29%	99% (180cc)

1970 - 72 U.S. Army Heidelberg

- 1600 consecutive ObGyn outpatients
  - 58% douched (W 55 % B 88 %)
  - 23% 2 - 3x / week
  - 24% 1 / week
  - 67% Douche bag

1970 - 72 U.S.Army Heidelberg

- Douching vs. "yeast" infection - NS
- Of patients douching - MD recommendation
  - 25% of those without infection
  - 40% of those with infection
- 400 patient subset

7 with pain on douching
3 with history of PID
Pre-operative douching - methylene blue
No fluid above internal os
1930 Karanaky - douching with radiographic fluid with pressures
>200 mmHg - No retrograde flow

1974 - 76 Suburban Washington, D.C.
Elective laparoscopic sterilization 226 patients
47% douched
Pain with douching - 6 patients
3 pelvic varicosities, 2 negative pelvis, 1 endometriosis
Patients with IUD's vs. douching
Surgical findings of PID - NS

1988 60 patients with ectopic pregnancy
43% douching 23% weekly
63% post-coital / menses
58% disposable douches
Use of feminine sprays and powders 2x that for patients douching

1992 U.S. Navy Portsmouth, VA

440	BTO		56	Ectopic	
	B	W	B	W	
Douche	70%	47%	75%	56%	
Post-coital	14%	12%	7%	21%	

SAS Computer Analysis
T-test / Linear Regression Analysis

1992 Study - Significant Findings
Douching frequency, not incidence, related to surgical PID and ectopic pregnancy
Patients with no surgical PID and no ectopics and no hx STD
White - were less likely to douche
Black - were more likely to douche
Women reporting vaginal infections douched less frequently

Douching Frequency
Associated:
Fewer vaginal infections
Ectopics (0 vs. 1)
Ectopics + White
Ectopics + hx PID + White

Ectopic + hx PID + hx STD + White

Not Significant

PID / perihepatic adhesions / STDs / race

Frequency / STD / PID / ectopic vs. IUD

Inconsistencies:

Stock - change in douching methods / incidence PID & ectopics

Vaginal infections not related to douching

Opposite effects as related to race

Chow, Daling 1985 Ectopics

Risk greater for commercial douches

? Delivery systems ?

Agreed to study - 61.5% / LFU - 27.9%

Chow, Daling 1988 Ectopics

Douching examined - No results regarding relationship ??

Wolner-Hanssen 1990 PID

As number of sexual partners increased OR (related to douching) decreased

Surgical Diagnosis of PID 1992 / Stock

Statistically significant association

Blacks / Hispanics

Clinical history PID

Length of infertility

Pelvic pain

Ectopic Pregnancy1992 / Stock

Related

STD Infertility + STD

Number of partners (1+)

Smoking (1+)

Never married

Multiple marriages (2+)

Longer infertility

Menstrual pads (2+)

Summary

There is some evidence for an association between frequency of vaginal douching and PID + ectopic pregnancy

Is the association because:

1) Douching promotes problems?
2) Sexual behavior, cervical ectopy, STDs, or MD's recommendations, promote douching

There is no evidence supporting douching as a causative factor for vaginitis, PID or ectopic pregnancy, i.e., no detrimental effect

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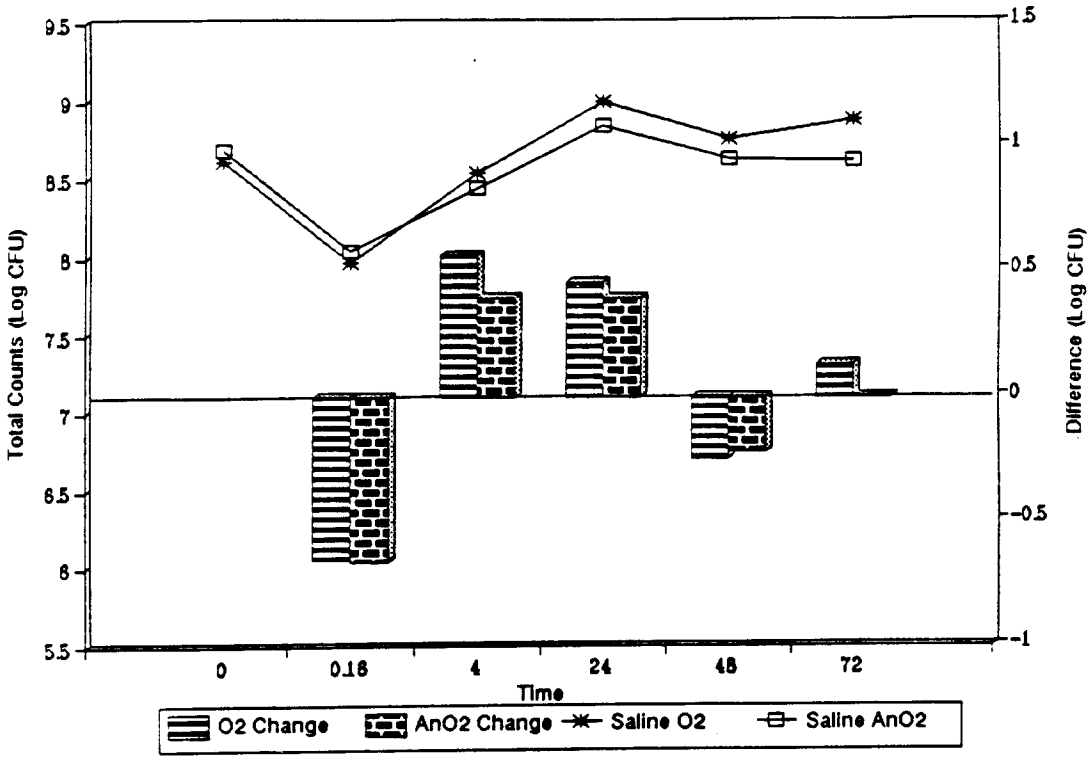
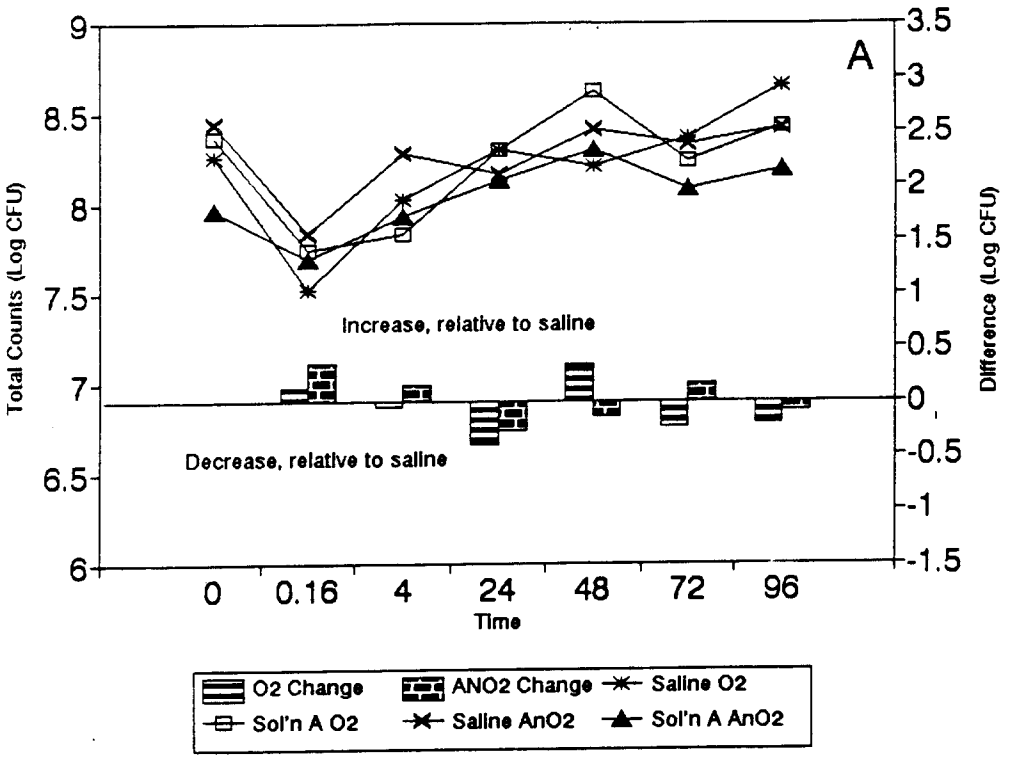
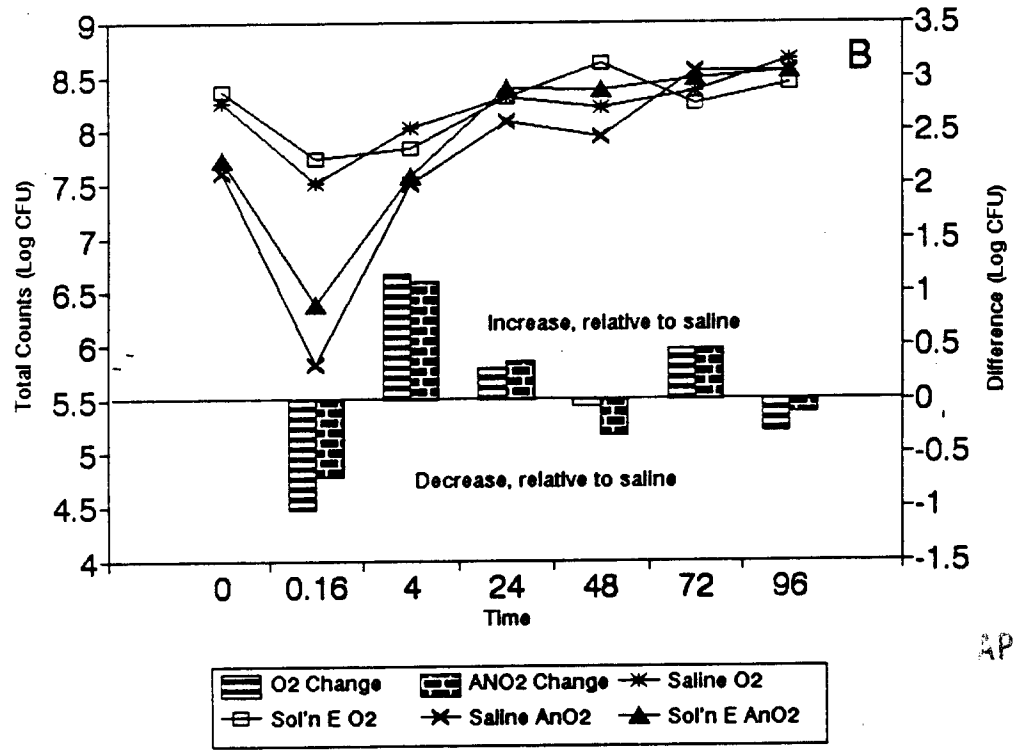
- "Vaginal Douching ?Association or Causation? for PID and Ecceysis" Stock, R.J.

Onderdonk, Slide #1



Total counts and log difference between sample time following the use of saline.





(A) Total counts and log difference between sample times normalized for saline following seven day use of solution A (Vinegar and Water).
(B)Total counts and log difference between sample times normalized for saline following seven day use of solution E (Povidone Iodine).

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ISOLATION FREQUENCY[a] AND MEAN COUNT[b] BY PRODUCT AND SAMPLE TIME

Time (hr) / Organism	0	.16	4	24	48	72	96
SALINE							
Lactobacillus species	100(8.20)	100(7.30)	100(7.87)	100(8.25)	100(8.21)	100(8.22)	100(8.59)
Unid. Gram + Aerobe	80(4.68)	60(4.41)	80(4.75)	80(4.75)	90(4.74)	90(4.52)	80(4.97)
Bacteroides species	40(5.22)	40(5.79)	40(5.61)	60(5.60)	40(6.98)	50(5.35)	40(6.85)
Gardnerella vaginalis	20(9.25)	20(8.81)	20(9.01)	20(9.28)	20(8.92)	20(9.15)	20(9.14)
Escherichia coli	10(4.40)	10(3.81)	40(3.74)	20(3.41)	10(4.00)	10(3.49)	20(4.63)
Group B *Streptococcus*	ND[c]	ND	ND	ND	ND	ND	ND
SOLUTION A[d]							
Lactobacillus species	100(8.26)	100(7.67)	100(8.08)	100(7.99)	100(8.23)	100(8.16)	100(8.28)
Unid. Gram + Aerobe	60(5.19)	60(5.01)	60(5.03)	70(4.91)	80(5.08)	70(4.83)	70(5.43)
Bacteroides species	70(4.54)	40(5.13)	30(5.25)	50(5.39)	30(5.94)	40(5.68)	30(6.24)
Escherichia coli	30(4.13)	20(3.79)	ND	10(3.15)	20(5.04)	20(4.43)	10(5.42)
Gardnerella vaginalis	10(10.04)	10(10.11)	10(9.62)	10(9.68)	20(8.67)	10(9.33)	10(9.53)
Group B *Streptococcus*	10(7.48)	10(7.29)	10(7.31)	10(5.01)	ND	ND	ND
SOLUTION E[e]							
Lactobacillus species	100(7.58)	80(6.23)	90(7.49)	90(8.07)	90(7.91)	80(8.46)	80(8.25)
Unid. Gram + Aerobe	60(4.72)	40(4.26)	60(4.66)	60(4.79)	60(4.60)	40(5.81)	50(6.00)
Bacteroides species	40(5.16)	20(4.12)	40(4.89)	30(5.71)	30(4.35)	10(3.76)	40(5.26)
Escherichia coli	30(4.03)	ND	ND	10(3.62)	10(4.23)	ND	10(3.67)
Gardnerella vaginalis	10(7.13)	10(5.28)	10(7.08)	10(7.19)	10(7.30)	10(8.48)	10(7.63)
Group B *Streptococcus*	10(5.53)	10(5.36)	10(5.20)	ND	ND	ND	ND

[a]Percentage of samples from which organism was recovered, N=10 at each sample time.
[b]Mean count expressed as Log_{10}CFU per gram.
[c]No organism detected.
[d]Solution containing 0.40% of 10% acetic acid
[e]Solution containing 0.30% povidone iodine.

Onderdonk, Slide #4

Generalized Estimating Equation (GEE)

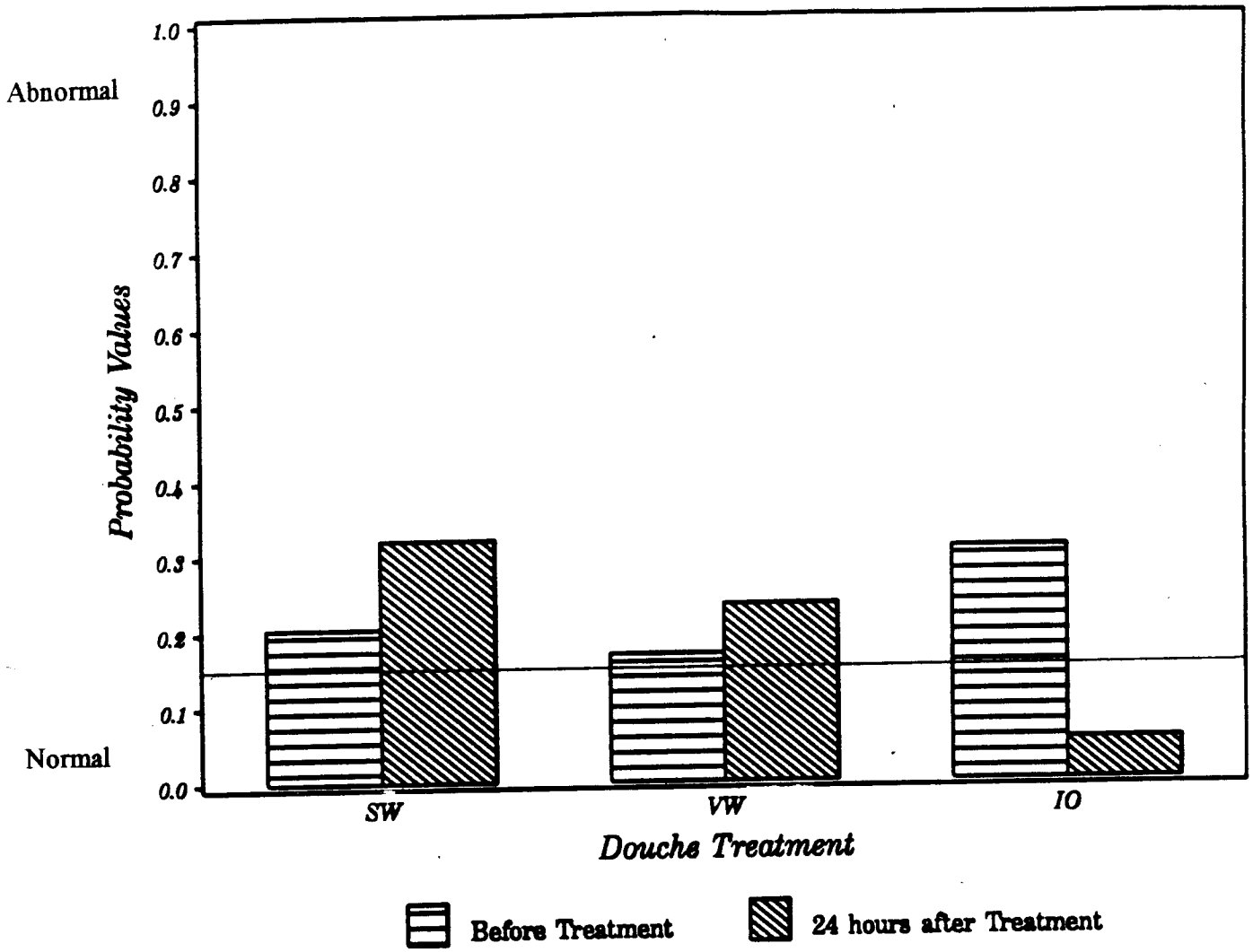
$$\text{logit}\,(p(t)) = 1.06 - 0.53 \times PH - 0.84 \times STP + 0.16 \times TAB + 0.30 \times LAC - 0.23 \times PREV$$

This links the logit of the probability of having abnormal microbial concentrations at time *t* with the corresponding pH and other explanatory risk factors:

STP: *Streptococcus* count ($\log_{10}$ CFU/G of sample).
TAB: Total aerobe count ($\log_{10}$ CFU/G of sample).
LAC: *Lactobacillus* count ($\log_{10}$ CFU/G of sample).
PREV: *Prevotella* count ($\log_{10}$ CFU/G of sample).

Onderdonk, Slide #5

Average Values for the Probability of Abnormality



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NATIONAL WOMEN'S HEALTH NETWORK

Vaginal Douching
Nonprescription Drugs Advisory Committee
April 15, 1997

Lisa Cox, Program and Policy Director
National Women's Health Network

Good afternoon, members of the committee. My name is Lisa Cox, Program Director of the National Women's Health Network, an advocacy organization supported by 13,000 individual and 300 organizational members. The Network accepts no financial support from pharmaceutical companies or device manufacturers.

I appreciate the opportunity to come before you today to give you the Network's perspective on the issue of douching, and I want to commend the Advisory Committee and the Agency for beginning to look at and address this very important issue.

Douching products figure prominently in the marketplace of goods and services targeted to women's health, and it is critical that we identify the possible relationship between douching, pelvic inflammatory disease and decreased fertility in the best interests of speed this information to women.

Although the committee has not been charged with making recommendations as to the safety and effectiveness of douching products, the Network believes that douching has no beneficial effect on women's health and appears to enhance the chances of developing upper reproductive tract infections, PID, ectopic pregnancy and infertility.

For women trying not to get pregnant, it is not an effective contraceptive, and douching can compromise fertility in women trying to get pregnant. Douching can change the vaginal environment and can mechanically wash out sperm. In a study of 840 married women with children conducted in King County, Washington, women who douched were 30% percent less likely to become pregnant each month they attempted pregnancy as compared to women who did not douche (Baird, Voigt, Daling, 1996). Further, this reduction in fertility was greater for younger women than for older women.

Douching can also compromise fertility by driving bacteria from the vagina into the uterus and fallopian tubes, turning a vaginal or cervical infection into an upper reproductive tract infection with much more serious ramifications that may include infertility, chronic pelvic pain, and adhesions.

A study conducted in 599 pregnant women in Indonesia, in which nearly 20% percent had a sexually transmitted disease, found that douching with water and soap or a commercial agent after sex was associated with PID. This relationship was amplified if the women douched before or before and after sex. Other studies have shown that douching is associated with a doubling of risk for PID (Scholes, et al.) and ectopic pregnancy (Chow, et al.).

The Network believes that while women may feel that they need to douche, there is no medical benefit in doing so. Women should be told of the adverse affects of douching, as many cases of PID and infertility could be prevented by increasing information to women. The FDA, in partnership with other branches of the Public Health Service should consider implementing a public education campaign to make women aware of this issue.

Thank you once again for the opportunity to share the Network's perspective with the committee.

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