

Teaching Epidemiology: Methods, although sophisticated, are not enough (or, DAG-less in a causal inference world)

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School of Public Health

Teaching Epidemiology

- Epidemiological, biostatistical, and causal inference methods are continually evolving
- Students expect, demand, and need the most up-to-date methods

Question

Can “epidemiologists” who can’t draw a DAG (i.e. Directed Acyclic Graph) still make a contribution to the teaching of epidemiology?

Imperfect Studies in an Imperfect World: Lessons Learned by an Autodidact

- Arthur L. Reingold, MD
- President, Society for Epidemiologic Research (SER) 2009-2010

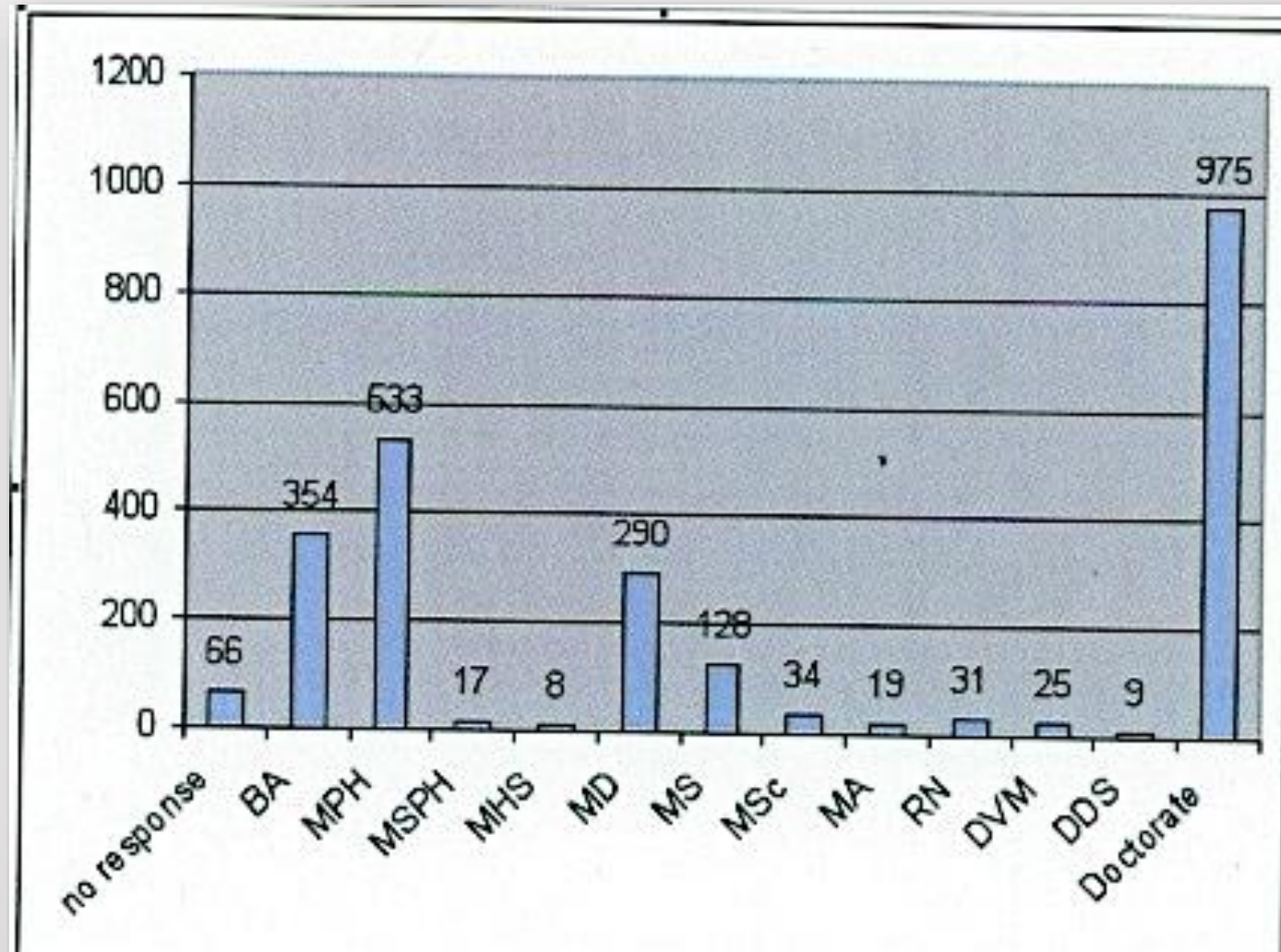
Autodidact

- One who is self-educated

Arthur Reingold's Education and Training

- 1970: BA (Biology)
- 1976: MD
- 1976-1978: Residency, Internal Medicine
- 1979-1981: Epidemic Intelligence Service, CDC
- 1981-1982: Preventive Medicine Residency, CDC

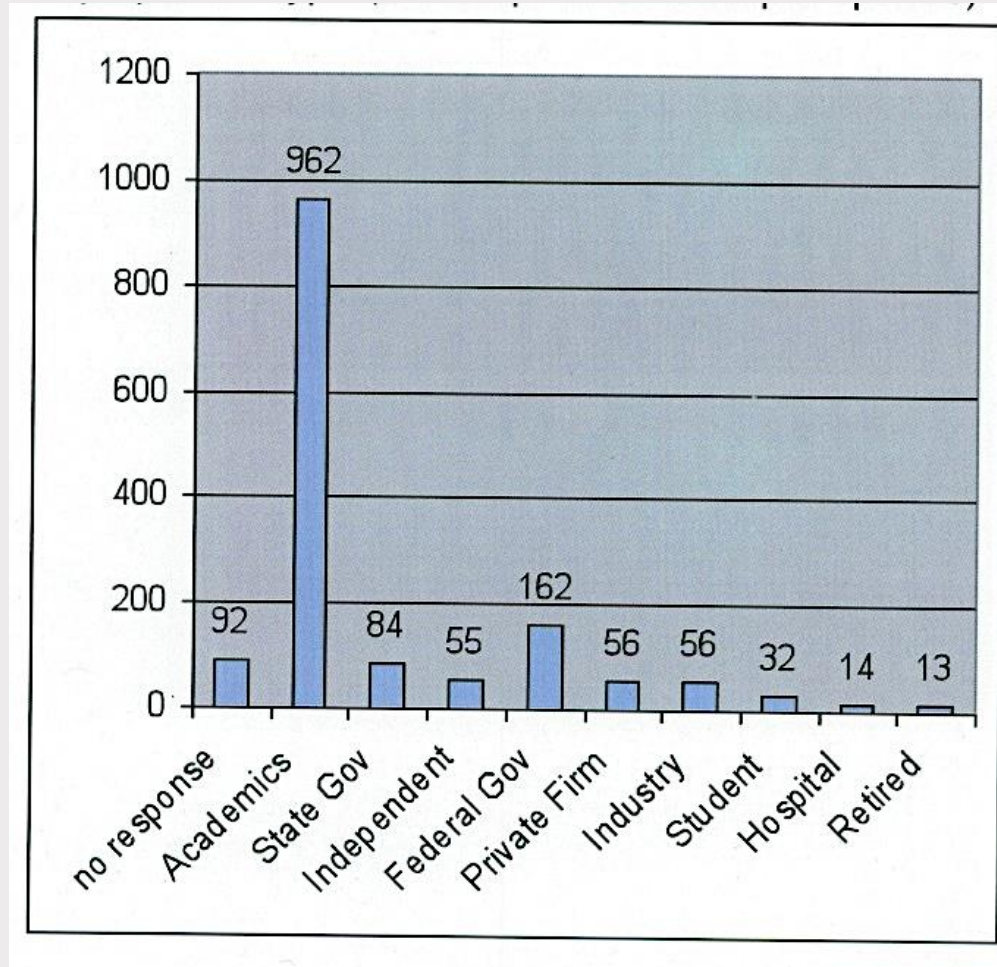
Disciplinary Training of SER's Members, 2008



Arthur Reingold's Public Health Work Experience

- Local/County Health Department:
 - San Francisco Department of Public Health
- State Health Department:
 - Connecticut State Department of Health
- National:
 - Centers for Disease Control and Prevention (CDC)
- International:
 - Multiple Ministries of Health and the World Health Organization (WHO)

Employment Type of SER's Members, 2008



Self-Educated or Uneducated?

- “If he doesn’t have a brain, how did he get to be a professor?”

University of California, Berkeley

Epidemiology Graduate Student Satirical Skit

Circa 1992

Teaching Epidemiology (cont.)

Students also need to learn:

- How to come up with important, but answerable questions
- How to “think epidemiologically”
- The importance of optimal study design and implementation
- Other life skills

Epidemiology-Definition

- 1850's: *“Branch of medical science which treats epidemics.”*

London Epidemiological Society

- 2017: *“The study of the distribution and determinants of health-related states or events in specified populations and the application of the study to control health problems.”*

J. Last, Dictionary of Epidemiology

Epidemiology-Objectives

- Study the natural course of disease
- Determine the extent of disease in a population
- Identify patterns and trends in disease occurrence
- Identify the causes of disease
- Evaluate the effectiveness of measures that prevent and treat disease

Aschengrau and Seage
Essentials of Epidemiology in Public Health

Epidemiology-Components

- Descriptive
- Analytic

Epidemiology-Toolbox

Analytic Experimental Study Designs

- Individual Level (i.e. individual randomized)
- Group Level (i.e. cluster randomized)

Parachute use to prevent death and major trauma related
to gravitational challenge: systematic review of
randomised controlled trials

Gordon C S Smith, Jill P Pell

BMJ, 2003

The NEW ENGLAND JOURNAL of MEDICINE

REVIEW ARTICLE

THE CHANGING FACE OF CLINICAL TRIALS

Jeffrey M. Drazen, M.D., David P. Harrington, Ph.D., John J.V. McMurray, M.D., James H. Ware, Ph.D.,
and Janet Woodcock, M.D., *Editors*

Evidence for Health Decision Making —
Beyond Randomized, Controlled Trials

Thomas R. Frieden, M.D., M.P.H.

NEJM, 2017

Epidemiology Toolbox (cont.)

Analytic Observational Study Designs

- Ecologic
- Cohort
- Cross Sectional
- Case-Control
- Case-Cohort
- Case-only/Case-Crossover

Articles

Scientific Standards in Epidemiologic Studies of the Menace of Daily Life

ALVAN R. FEINSTEIN

Science, 1988

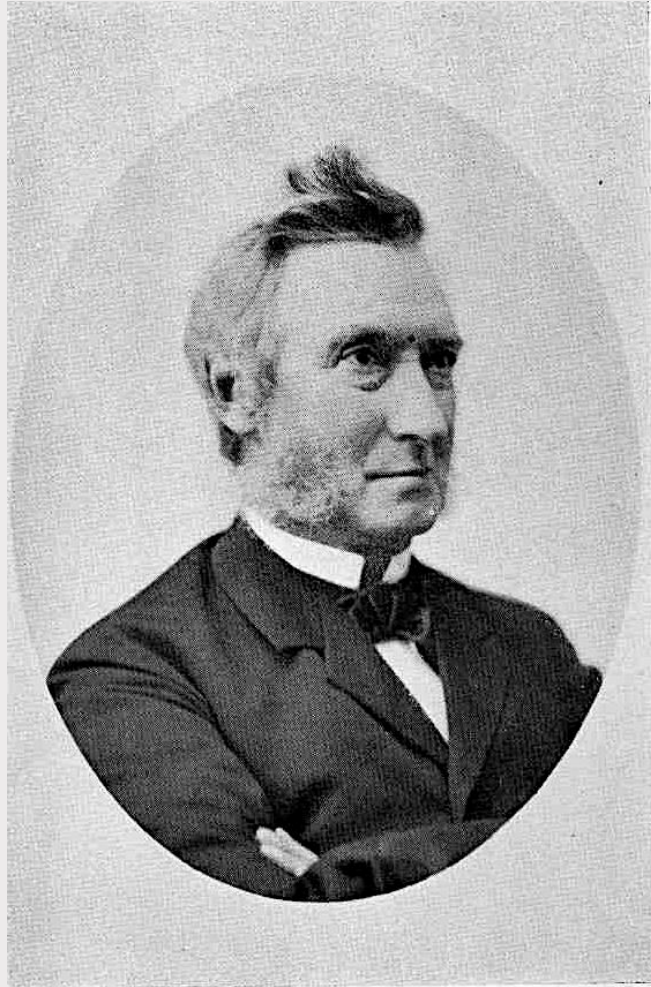
Some Noted Epidemiologists Who Never Drew a DAG

- Peter Panum
- John Snow
- Emile Durkheim
- Joseph Goldberger
- Richard Doll
- Arthur Herbst

Peter Panum

Peter Panum investigated measles on the Faroe Islands in 1846 and showed through epidemiologic investigation that:

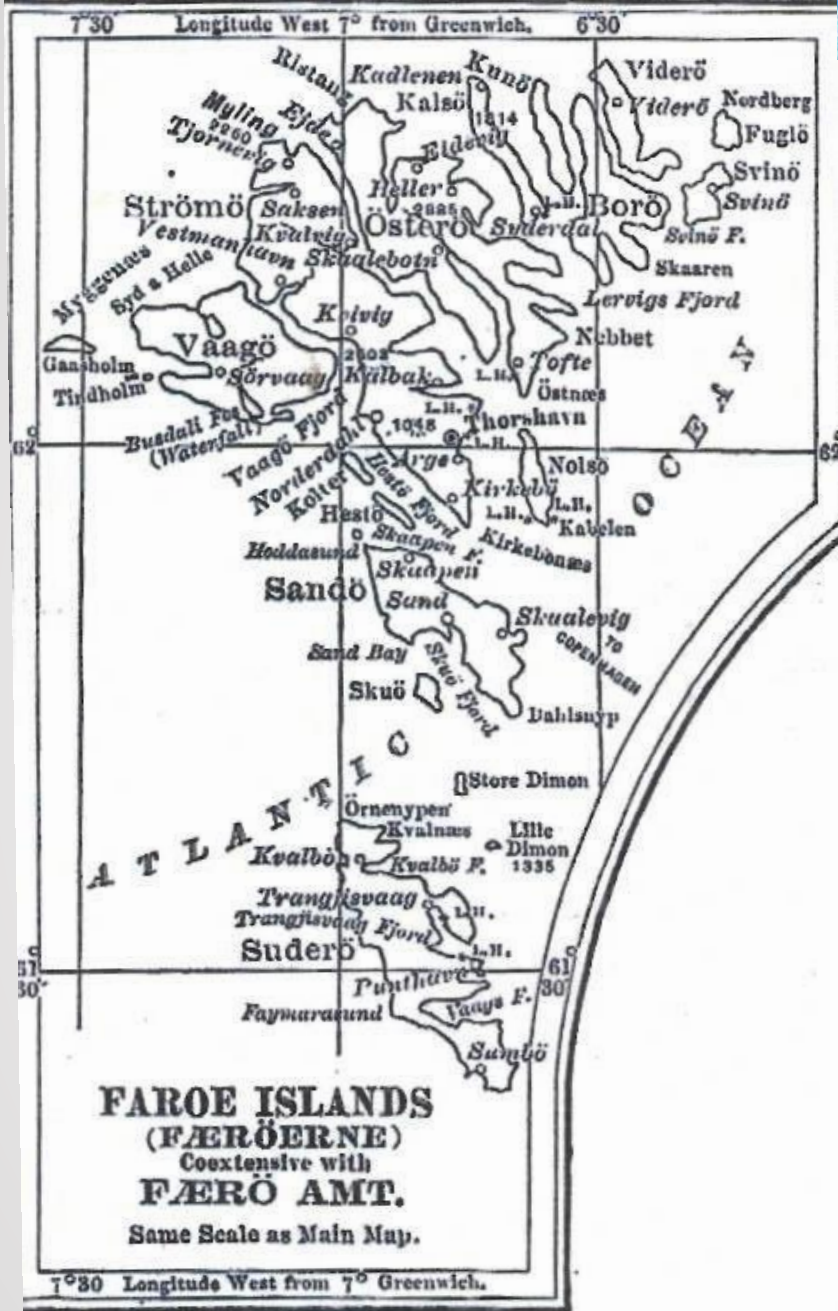
- Incubation period: 10-14 days
- Infectious stage = prodrome/early stage; not at time of desquamation
- Measles produces lifelong immunity
- Little or no spread via fomites
- Cases can always be linked to other cases--cases do not arise spontaneously.



PETER LUDWIG PANUM (1820-1885)

Reproduced through the kindness of Dr. Henry E. Sigerist, Editor, Bulletin of the History of Medicine.





. . . "The other dish, which, by the way, is eaten first, consists of 'rast,' that is, half-spoiled meat or fish. The same method of preserving meat which is used for lamb is used also for grind meat,* fish, or bird meat; all are hung up to dry without any preparation by salting, smoking, or the like. In the course of several months, when the meat (or fish) is neither fresh nor wind-dried, it is called 'rast,' a word that can be translated by no other term than 'half-rotten,' an epithet fully merited by this meat, considering the abominable odor it spreads, its unpleasing, mouldy appearance, and it's not infrequent occupation by maggots. This 'rast' meat is usually cooked before it is eaten, although some people prefer to eat it raw. I have seen a whole boat's crew (eight men) eating raw grind meat with great appetite,

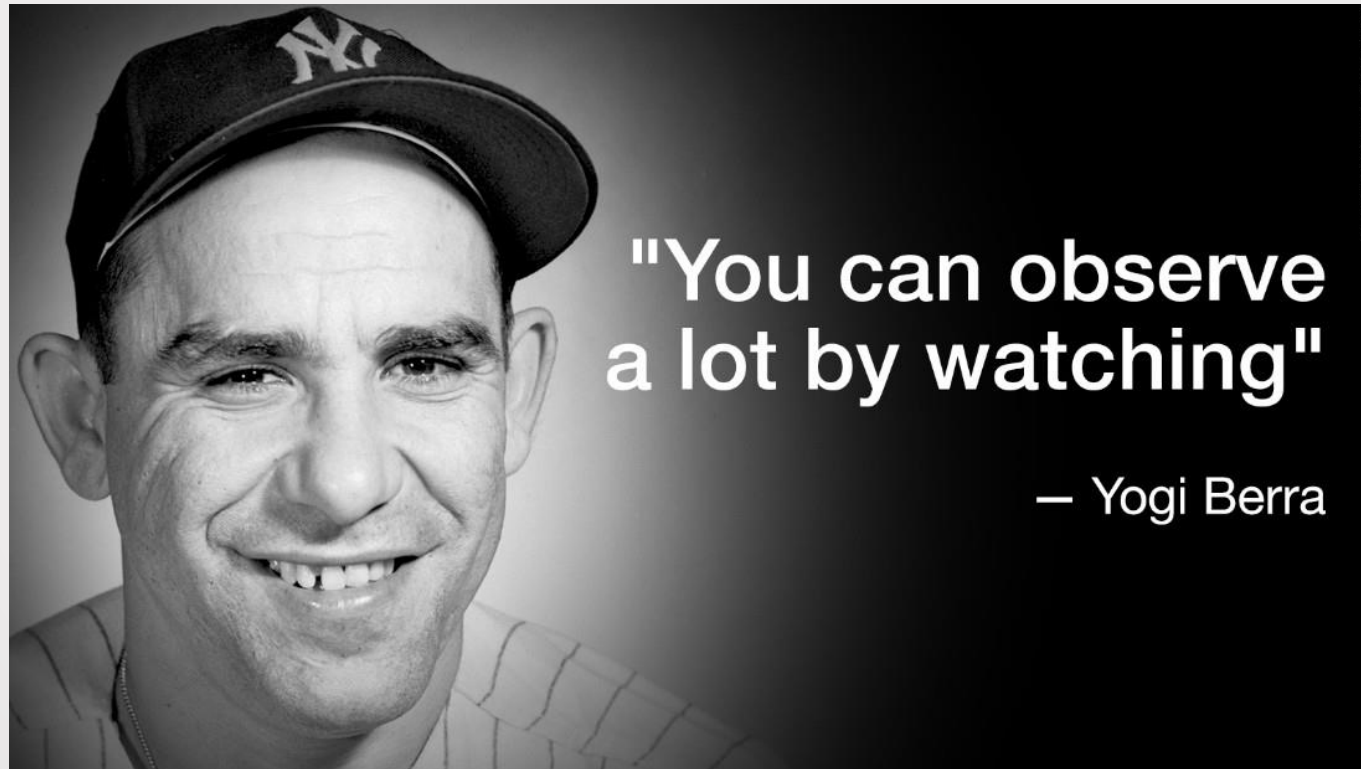
*Grind are a species of dolphin, which swim around the shores in great schools of 100 to 1000, and which, when a school strays into a fjord, are driven upon the shore and killed; such a grind drive is the greatest delight of the Faroese.



. . . "We have already referred to the clothing, which does not adequately protect the body from the rigors of the climate. We need therefore make no further mention of it here except as regards its uncleanness. That, as a rule, it is of woolen stuff outside and inside is certainly in conformity with its purpose, as far as the climate is concerned; but it is clear also that vermin, for instance lice, and itch mites, thrive in the woolen shirts which are seldom changed. The odor which the clothes of the Faroese acquire from the fact that they wash their garments in urine, whereof the production of the whole family is preserved in a great vat, appears to be not unpleasant to these small animals; at any rate itch is an extremely common disease, and very few

Yogi Berra (1925-2015)

Catcher, New York Yankees



Example of Other “Yogiisms”

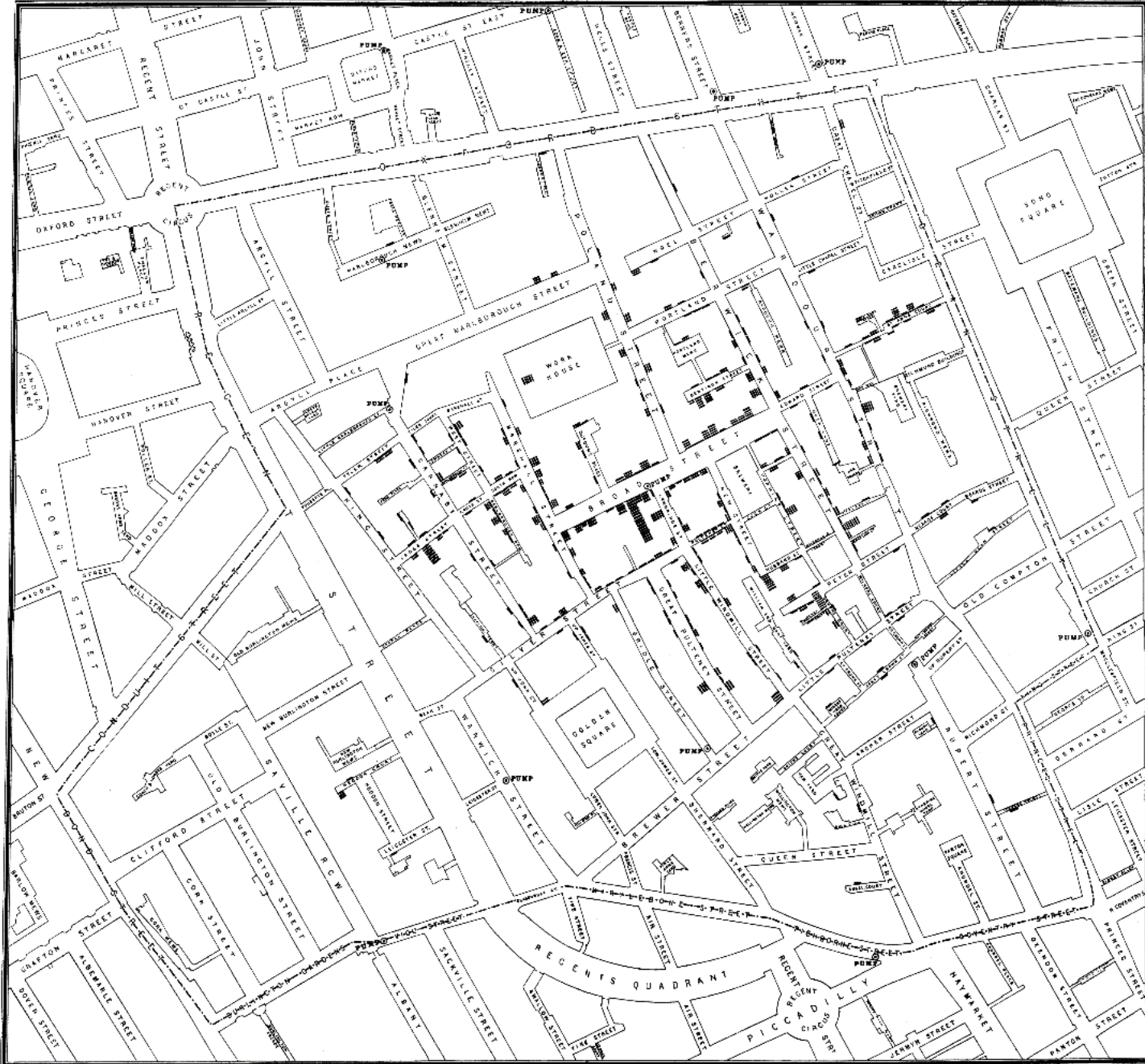
- “Always go to other people’s funerals; otherwise they won’t go to yours.”
- “Pair up in threes.”
- “What time is it? You mean now?”

John Snow

Investigated multiple outbreaks of cholera in London in the 1840s and 1850s

- Descriptive Study
- Analytic Study

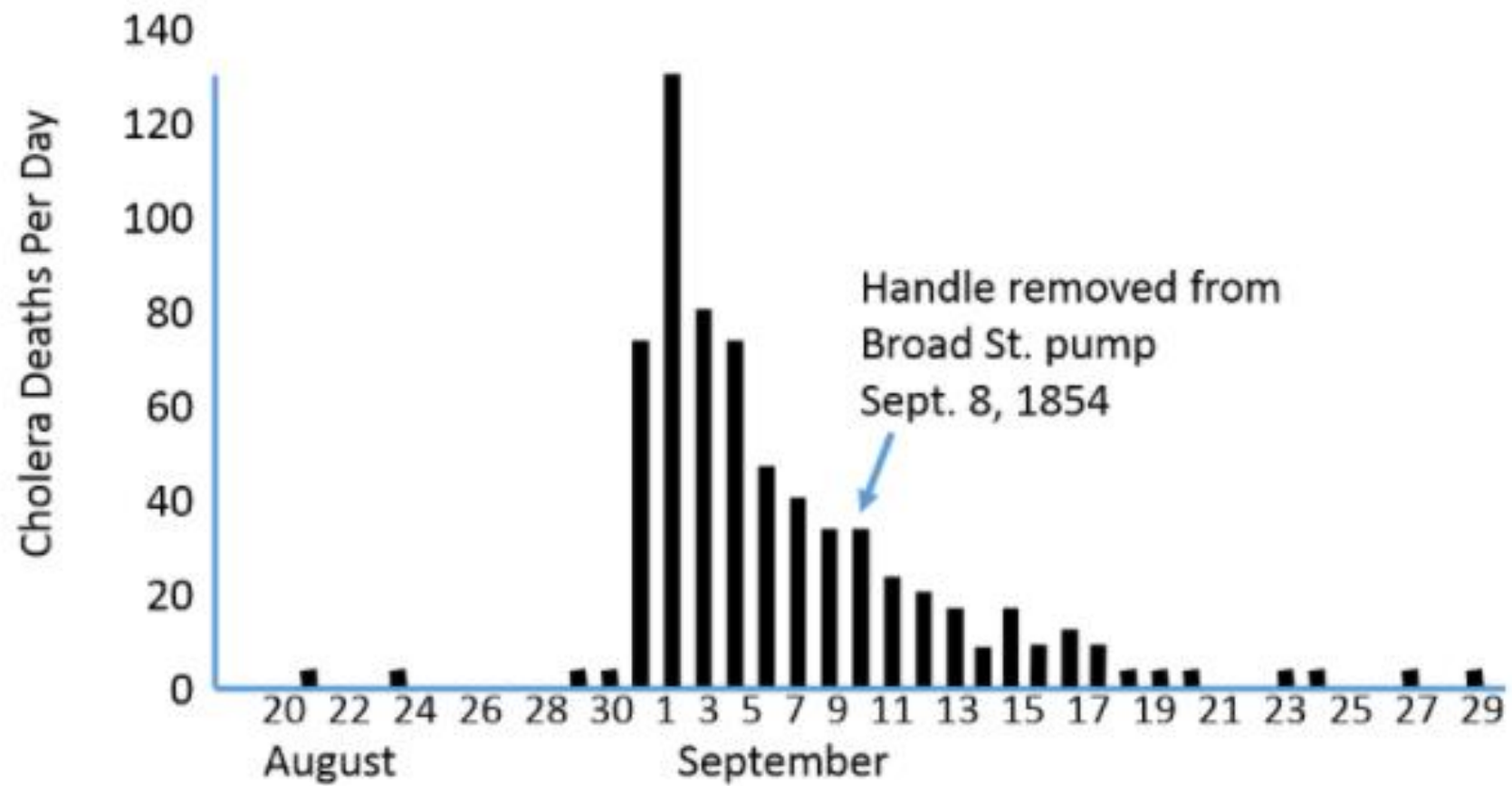


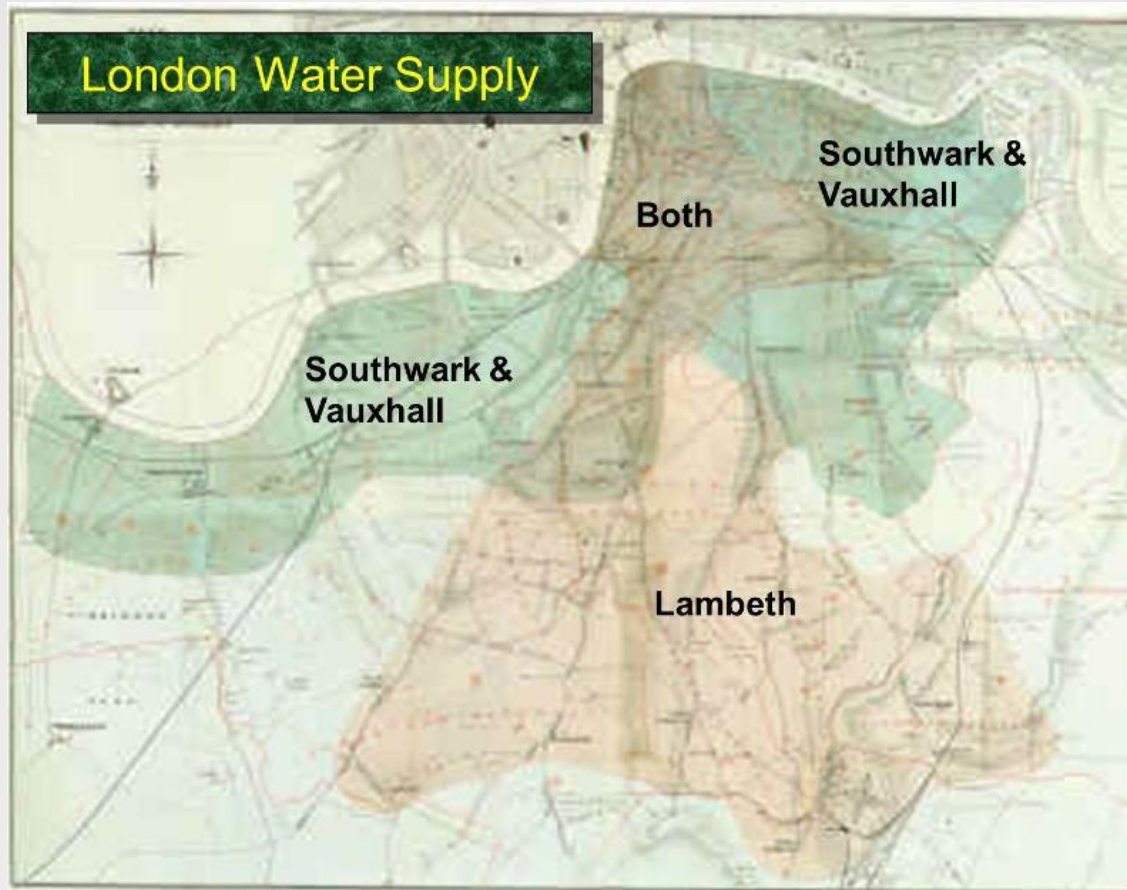


Many Londoners received their water from hand pump wells that were located throughout the city.



However, increasing numbers of businesses and homes had water piped from the Thames River by private companies. Snow learned from municipal records that two private companies supplied piped in water to the areas that were primarily affected by cholera.





Water Company	# Houses Served	# Cholera Deaths	Death Rate per 10,000 Houses
Southwark & Vauxhall	40,046	1,263	315
Lambeth	26,107	98	37
The Rest of London	256,423	1,422	59

Emile Durkheim

- Investigated suicide in Europe in the 1880's
 - Ecologic Study

Ecologic Studies - Example: Suicide and Religion, Prussian Provinces (1883-1890)

Proportion of Population in the Provinces that is Protestant	Suicides per Million Inhabitants
> 90%	264.6
58 - 89%	220
40 - 50%	163.6
28 - 32%	95.6

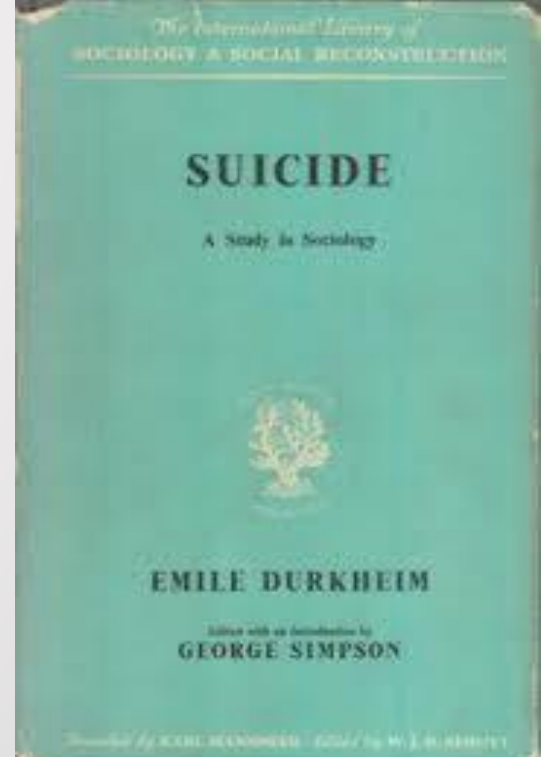


Durkheim

Suicide: A Study in Sociology 1897

Durkheim's Views

- “If one casts a glance at the map of European suicide, it is at once clear that in purely Catholic countries like Spain, Portugal, and Italy, suicide is very little developed, while it is at its maximum in Protestant countries, in Prussia, Saxony, Denmark.”
- “Nevertheless, this first comparison is still too summary. In spite of undeniable similarities, the social environments of these different countries are not identical. The civilizations of Spain and Portugal are far below that of Germany and this inferiority may conceivably be the reason for the lesser development of suicide which we have just mentioned.”
- “. . .the proclivity of Protestantism for suicide must relate to the spirit of free inquiry that animates this religion.”
-



Suicide and Education, Italian Provinces, 1864-1876



Proportion of Marriages in the Provinces with Both Husband and Wife Literate	Suicides per Million Inhabitants
39.09%	41.1
15.23%	32.5
6.23%	14.7

Durkheim

Suicide: A Study in Sociology 1897

Durkheim's Views (continued)

“Further, we have seen that in all countries of the world women commit suicide much less than men. They are also much less educated. Fundamentally traditionalist by nature, they govern their conduct by fixed beliefs and have no great intellectual needs.”



Joseph Goldberger

Investigated pellagra in the southeastern U.S.,
early 20th Century

- Ecologic Study
- Cohort Study

Goldberger, Pellagra Findings

- Incidence rate does not correlate with sanitary rating
- Seasonality (peaks in early summer)
- Varies by age, sex, and marital status (of women)
- Clusters in households
- Associated with poverty
- Presence of certain foods in the house associated with a lower risk

Richard Doll

Investigated lung cancer and smoking, ~1951-1991

- Cohort Study
- Case-Control Study



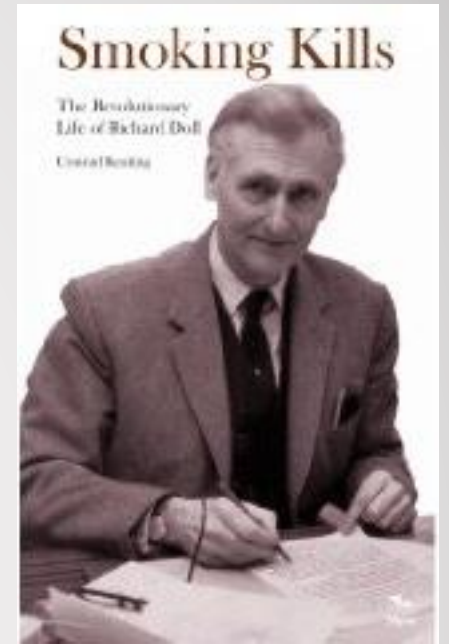
British Doctors Study



- **1951:**

Questionnaires about smoking habits sent to all registered physicians in the United Kingdom; complete replies returned from 6,194 women and 34,439 men. Follow-up in 1957, 1966, 1972, 1978, and 1990

British Doctors Study



- Follow-up Procedures, 1951-1991
 - Periodic mail questionnaires to the doctors
 - Monitoring of deaths via the Office of Population Censuses and Surveys; obituary columns of the British Medical Journal and the Medical Directory
 - Correspondence with people living at the doctors' last known addresses and with people who knew them

Lung Cancer Deaths among British Male Physicians Aged 35 & Over: Mortality, Relative Risk, and Attributable Risk

Smoking Status	Person-Years at Risk	Lung Cancer Deaths	Annual Rate per 100,000 (Incidence Density)	Relative Risk (Rate Ratio)
Non-Smokers	15,107	1	7	--
Smokers	98,090	80	81	11.6

Lung Cancer among British Male Physicians ≥ 35 Related to Smoking Habits

Smoking Habits**	Person-Years at Risk	# of Deaths	Annual Rate per 1000* (Incidence Density)
Non-smokers	15,107	1	0.07
Light smokers	38,586	22	0.47
Moderate smokers	36,089	24	0.86
Heavy smokers	23,415	34	1.66

*Age adjusted **Light smokers (1-14gm daily); Moderate smokers (15-24gm daily); Heavy smokers (≥ 25 gm daily)

From Doll and Hill, 1956

Relative Risks (Rate Ratios)

- **Light Smokers:** $0.47/0.07 = 6.7$
- **Moderate Smokers:** $0.86/0.07 = 12.3$
- **Heavy Smokers:** $1.66/0.07 = 23.7$

Doll's Case-Control Study of Lung Cancer and Smoking

- Outcome
 - Cases: Individuals with histologically confirmed lung cancer (n=1357)
 - Controls: Individuals with no evidence of lung cancer (n=1353)
- Exposure
 - Average number of cigarettes smoked daily in recent past

Doll's Case-Control Study of Lung Cancer and Smoking

Disease Category

Smoking Status	Lung Cancer	No Lung Cancer (Control)
Yes	1350	1292
No	7	61
Total	1357	1353

$$\text{Odds Ratio} = \frac{ad}{bc} = \frac{1350 \times 61}{1292 \times 7} = \frac{82,350}{9,044} = 9.1$$

Doll's Case-Control Study of Lung Cancer and Smoking (continued)

# Cigarettes Smoked per Day	Disease Category	
	Lung Cancer	Controls
25+	340	182
15-24	445	404
1-14	565	706
None	7	61

Doll's Case-Control Study of Lung Cancer and Smoking (continued)

$$\text{O.R.} = \frac{\text{1-14 Cigarettes vs. None}}{61 \times 565} = 6.97$$
$$\frac{7 \times 706}$$

$$\text{O.R.} = \frac{\text{15-24 Cigarettes vs. None}}{445 \times 61} = 9.6$$
$$\frac{7 \times 404}$$

$$\text{O.R.} = \frac{\text{25+ Cigarettes vs. None}}{340 \times 61} = 16.3$$
$$\frac{7 \times 182}$$

Arthur Herbst

Investigated vaginal adenocarcinoma and in utero exposure to diethyl stilbesterol (DES)

- Case-Control Study

Study of Herbst

- Adenocarcinoma of the vagina and in utero exposure to diethyl stilbesterol (DES)
 - Cancer of the vagina very rare, particularly in women < 25 years of age
 - Between 1966 and 1969, seven cases in young women (15-22 years of age) seen in one hospital; an eighth case seen at nearby hospital
 - No similarities among cases regarding douches, tampons, or other vaginal irritants. Only 1 of 7 had initiated sexual activity, and none had used birth control.

Study of Herbst (cont.)

- **Cases:** 8 cases with histologically confirmed cancer of the vagina
- **Controls:** 4 controls per case, selecting females born within five days of the case and in the same hospital/on the same service
- No differences between cases and controls in maternal age, maternal smoking, breastfeeding, intrauterine x-ray exposure, or many other exposures.

Study of Herbst (cont.)

In utero exposure to DES	Cases	Controls
Yes	7	0
No	1	32

O.R. = ∞ ; $p < 0.00001$

Significant associations also found for having had a prior pregnancy loss and for bleeding in the current pregnancy.

NEJM, 1971

SPECIAL NEWS REPORT

Epidemiology Faces Its Limits

The search for subtle links between diet, lifestyle, or environmental factors and disease is an unending source of fear—but often yields little certainty

Science, Gary Taubes, 1995

Patricia Brasil, et al.

Investigated Zika virus infection in women in Rio de Janeiro, Brasil, 2015-2016

- Cohort Study

ZIKA VIRUS INFECTION IN PREGNANT WOMEN

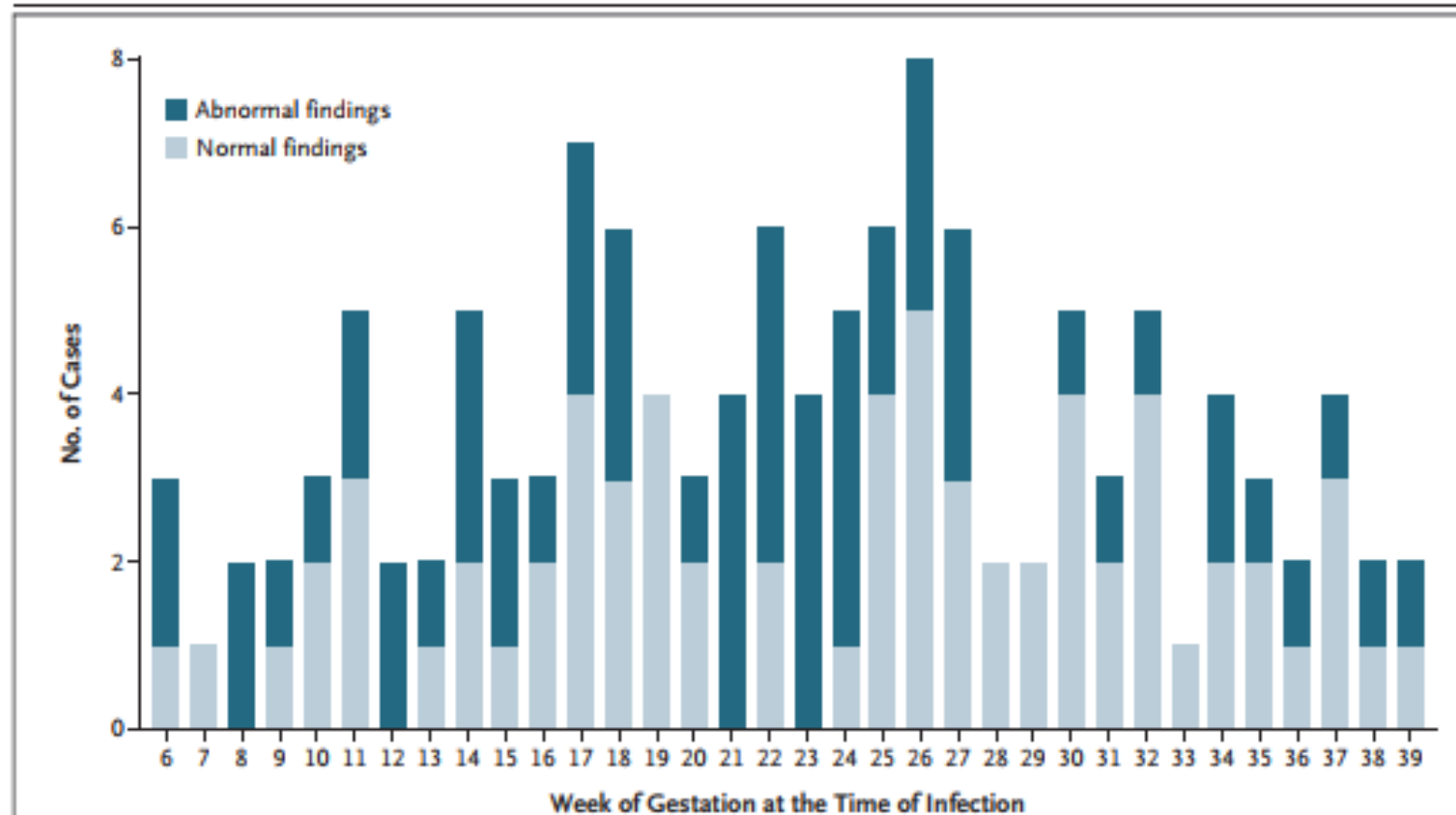


Figure 2. Pregnancy and Infant Outcomes According to the Week of Gestation at the Time of ZIKV Infection.

Adverse outcomes included 9 cases of fetal death in 125 pregnancies (7.2%) and 49 abnormal clinical findings, imaging findings, or both during the newborn period in 117 infants (42%) born from 116 pregnancies. Adverse outcomes occurred in women who were infected during the period from 6 to 39 weeks of gestation. Abnormalities are detailed in Table S2 in the Supplementary Appendix.

ZIKA VIRUS INFECTION IN PREGNANT WOMEN

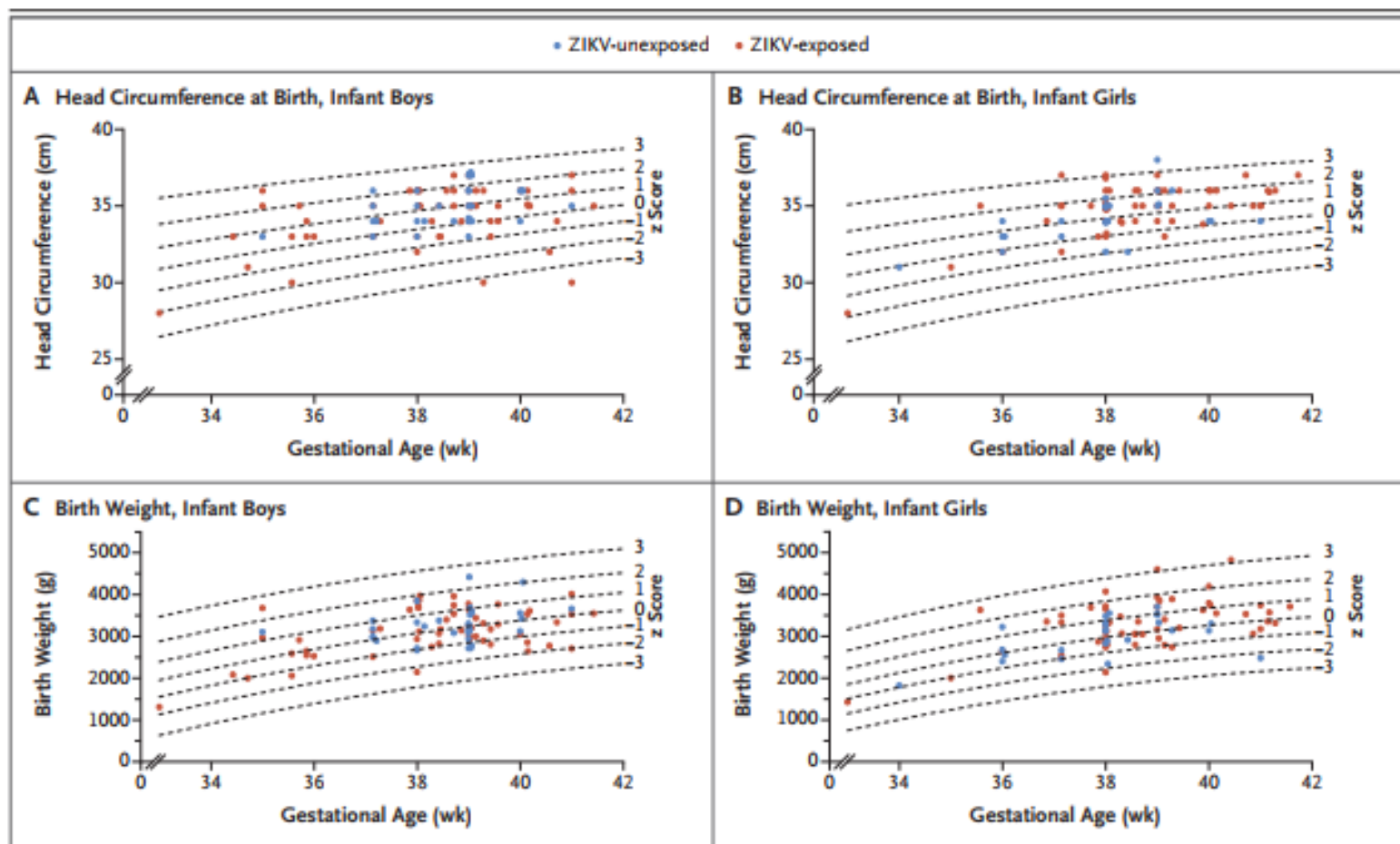


Figure 4. Infant Anthropometric Measures at Birth.

Shown are measurements of head circumference at birth in infant boys (Panel A) and girls (Panel B) and estimated birth weight in infant boys (Panel C) and girls (Panel D), according to gestational age at birth. A total of 117 live infants were born to women in our cohort who had positive results for ZIKV on polymerase-chain-reaction (PCR) assays, and 57 were born to women who had negative PCR results for ZIKV. Small for gestational age was defined as a z score for birth weight of less than -1.28 . Microcephaly was defined as a z score of less than -2 (moderate) and less than -3 (severe).

Zika Virus Infection in Pregnant Women and Adverse Infant Outcomes, Rio de Janeiro, 2015-16

	Adverse Infant Outcomes
Zika-exposed Live-Born Infants	49/117 (41.9%)
Zika-unexposed Live-Born Infants	3/57 (5.3%)

The “Education of Arthur Reingold”: Other Life Skills

- Hepatitis B transmitted by an oral surgeon
- Effectiveness of Meningococcal A vaccine
- Early detection of epidemics
- Menstrual Toxic Shock Syndrome and tampons
- Transmission of M. tuberculosis

Hepatitis B transmitted by an oral surgeon, Connecticut, 1979

- **Problem:**
Routine case report forms for 3 patients with acute hepatitis B - all mentioned recent dental work; when asked, all 3 patients had seen the same oral surgeon
- **Approach:**
Historical cohort study of patients of the oral surgeon

Hepatitis Link to Dentist Under Study

By JANE SUDOL

MYSTIC — About 800 patients of an oral surgeon here have been asked to take free blood tests next week after a state epidemiologist discovered that eight of the surgeon's patients contracted hepatitis since the beginning of the year.

The state Department of Health Services this week mailed letters and questionnaires to all patients of Dr. Roger J. Harris, who opened an office on Cow Hill Road in October 1977. About 98 percent of the patients are from New London County, Dr. Arthur Reingold, a state epidemiologist in charge of the investigation, said Friday.

At the request of state officials, Harris has voluntarily closed his practice and surrendered his license while the state, with the help of the national Center for Disease Control of Atlanta, Ga., determines the source of the infection. Harris couldn't be reached for comment Friday, but his answering service said his office was closed for two weeks.

tients had been treated for hepatitis B, or serum hepatitis, since the first of the year.

Hepatitis is a viral infection of the liver with symptoms similar to those of a viral cold: fatigue, lack of energy, fever, chills, jaundice and muscular aches and pains. Some persons can have the viral infection and not have any symptoms.

Hepatitis B can be transmitted through contact with infected blood or needles. Reingold said Harris' needles were all disposable, "and all of his dental procedures were unquestionably good."

An oral surgeon could contract hepatitis from patients and infect other patients if he were to cut his hand while operating, Reingold said. "Twenty-five percent of all oral surgeons show evidence in blood tests of having or having had hepatitis. It's an occupational hazard and the most likely possibility here," Reingold said.

However, Reingold said this is the first time in Connecticut that state officials are investigating a suspected

with hepatitis and Dr. Harris. We won't have an answer for four to eight weeks," Reingold said.

Reingold said results of Harris' blood tests will be known at the end of next week. Free blood tests for patients will be conducted Sept. 29 from 9 a.m. to 2 p.m. at the Poquonnock Bridge Baptist Church in Groton.

If Harris' blood tests show he doesn't have hepatitis, Reingold said, "it is conceivable the eight patients have something else in common that we haven't found yet. Or one patient may have contracted it if he was operated on after a patient with hepatitis B. But it won't be as a result of poor technique," Reingold said.

Harris' patients are being asked to return question-

naires with information on whether they have had tattoos or have shared needles, work in hospitals or laboratories where there is a higher risk of contracting hepatitis, and if they have had any illnesses indicating hepatitis.

Reingold said records from Southeastern Connecticut hospitals will be exam-

ined to determine the number of cases for the physicians to report all patients who will be compared with other oral sur-

Table 2. Prevalence of seropositivity for markers of hepatitis B virus among non-institutionalized patients of a seropositive oral surgeon, by year of surgery

Year	No. of patients seropositive/no. tested (%)	P value*
1977	4/84 (4.8)	0.43
1978	15/204 (7.4)	0.02
1979	33/223 (14.8)	0.00001

NOTE. Seropositivity was defined as the presence of hepatitis B surface antigen or antibody to hepatitis B surface antigen.

*Calculated by binomial distribution. The expected value was 4.0%.

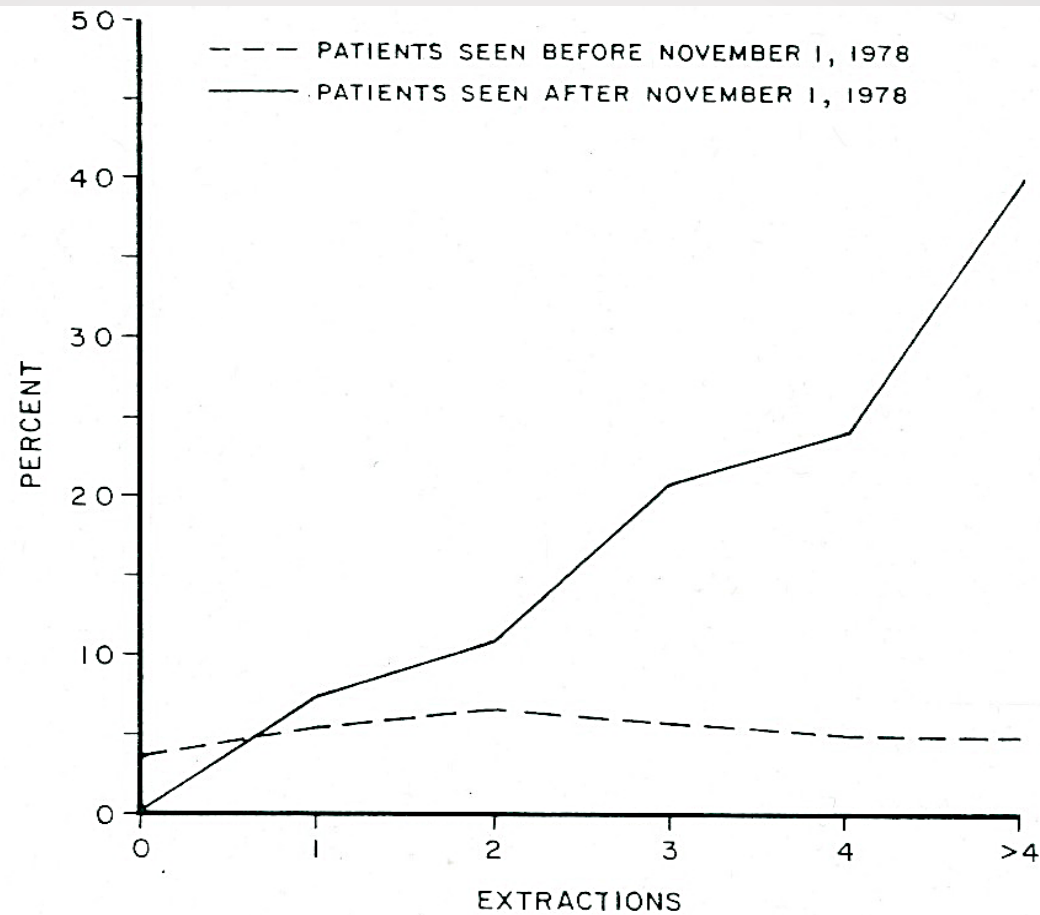


Figure 2. Comparison of the percentage of patients seropositive for a marker of hepatitis B virus among the noninstitutionalized patients of a seropositive oral surgeon and the number of tooth extractions. Seropositivity was defined as the presence of hepatitis B surface antigen or antibody to hepatitis B surface antigen.

Dentist Carries Disease; Board Suspends License

By DAVID H. RHINELANDER

The state Dental Commission has suspended indefinitely the practicing license of a Mystic oral surgeon who unknowingly transmitted hepatitis to at least 13 of his patients.

Dr. Roger J. Harris, 36, is a carrier of Hepatitis B, a viral blood infection, the commission said. He closed his practice voluntarily and surrendered his license in September after the hepatitis among his patients was discovered.

The commission said he still would be permitted to teach and be a consultant and administer anesthesia — one of his specialities — as long as he wears gloves and a mask and keeps detailed records.

Harris said Thursday he is looking for a teaching or a consultation job, but does not plan to have any direct patient contact.

He said he hasn't decided whether to seek experimental treatment for his

hepatitis. Carriers sometimes lose their infection spontaneously and a few medical centers are developing ways to treat carriers of hepatitis. Only a small percentage of hepatitis patients become carriers and the duration of that condition is unpredictable.

Harris opened his practice in Mystic 2½ years ago after completing military service and teaching dentistry. He suspects he contracted hepatitis while doing oral surgery on a resident of the state's Seaside Regional Center for the retarded in Waterford in March 1978.

State and federal epidemiologists, in a classic case of medical detective work, were able to match the specific subtype of B hepatitis in Harris with that in 13 of his patients. At least two members of the family of one of these patients also developed hepatitis. Another dozen patients showed evidence of past hepatitis infection that may have come from Harris, according to the experts.

Hepatitis B transmitted by an oral surgeon, Connecticut, 1979

- Lesson Learned:
Be cautious (our findings have impact)

Epidemic Meningococcal Meningitis, West Africa, 1982-1984

- **Problem:**
Extensive use of serogroup A polysaccharide vaccine in 1981;
unknown duration of vaccine-induced protection
- **Approach:**
Case-control study of vaccine effectiveness

Epidemic Meningococcal Meningitis, West Africa, 1982-1984

- Results:
Vaccine-induced protection lasted at least three years when vaccine was given to older children (≥ 4 years of age); it lasted only one year when given to younger children and infants (1, 2, and 3 year olds)

Epidemic Meningococcal Meningitis, West Africa, 1982-1984

- Lesson Learned:
Be selective (in your choice of mentors)

Epidemic Meningococcal Meningitis, Nepal (and back in West Africa), 1983-84 and beyond

- **Problem:**

Meningitis epidemics occur unpredictably; late detection and delayed response leads to increased morbidity and mortality

- **Approach:**

Use of routine surveillance data in models to examine performance characteristics of various threshold rates to predict epidemics

Epidemic Meningococcal Meningitis, Nepal (and back in West Africa), 1983-84 and beyond

- **Results:**
Sensitivity, specificity, and positive- and negative predictive values of various weekly rates of meningitis for predicting impending epidemics estimated and optimal rate identified; incorporated into WHO guidelines and country programs

Epidemic Meningococcal Meningitis, Nepal (and back in West Africa), 1983-84 and beyond

- Lesson Learned:
 - Be humble (someone else has always done it before)

An Assessment of the Use of Bayes' Theorem for Forecasting in Public Health: the Case of Epidemic Meningitis in China

GUANG ZENG*, STEPHEN B THACKER**, ZHEN HU†, XIUJIN LAI‡ AND GUIKUN WU‡

Zeng G (Institute of Epidemiology and Microbiology, Chinese Academy of Preventive Medicine, Peking, China), Thacker SB, Hu Z, Lai X and Wu G. An assessment of the use of Bayes' Theorem for forecasting in public health: the case of epidemic meningitis in China. *International Journal of Epidemiology* 1988, 17: 673-679.

A mathematical model based upon Bayes' Theorem (BT) was used to forecast the occurrence of epidemic cerebrospinal meningitis (ECM) in ten communities in North China. Reports of ECM from each ten-day period during the meningitis season and records of special population movement during 1960-82 were analysed to establish forecast models. Calibration, split-sample, random-sample selection, as well as actual forecast tests, were used to check the efficiency of the models. For all the tests, the theoretical occurrence of ECM forecast by the BT method was compared with the observational data. Since the BT method offers efficiency and convenience, it is recommended for use in planning for the prevention and control of ECM in China.

Epidemic Meningococcal Meningitis, Nepal (and back in West Africa), 1983-84 and beyond

- Lesson Learned:
 - Be well dressed (appearances matter)



Menstrual Toxic Shock Syndrome and Tampons, 1980

- **Problem:**
Increasing number of cases of Staphylococcal Toxic Shock Syndrome (TSS) in young women during menstruation; risk factors unknown
- **Approach:**
Case-control study of risk factors

Menstrual Toxic Shock Syndrome & Tampons, 1980

- **Results:**

Strong association with tampon use in general and with *Rely*[®] brand tampon use in particular

Findings attacked by industry-paid consultants and lawsuits filed demanding names of study participants

Stakes High in First Trial on Link Between P&G's Rely, Toxic Shock

By DEAN ROTBART

Staff Reporter of THE WALL STREET JOURNAL

The first trial alleging that Procter & Gamble Co.'s Rely tampon is linked to toxic-shock syndrome starts in Denver tomorrow. The stakes are high, and both sides may play rough to make their case.

The plaintiff is Deletha Dawn Lampshire, an 18-year-old student from Littleton, Colo., who survived her bout with the rare disease two years ago, but wants \$25 million from P&G. Her attorneys will put her on the stand to describe her ordeal, even though that means she may be rigorously cross-examined—even, possibly, on her sexual activities.

P&G faces more than 400 other Rely-related suits involving billions of dollars in damage claims. The Denver trial could set a precedent for other court tests, giving P&G, if it wins, some leverage in resolving other cases out of court—or, if it loses, making it easier for other plaintiffs to press their case.

Fielding Questions

As a public relations matter, the case is shaping up as a mini-version of the Ford Motor Co. Pinto trial, even though P&G, unlike Ford, isn't charged with "criminal negligence." The company is so concerned about the trial that it is abandoning its usually closed-mouth attitude and is assigning two public-relations people. They will be armed with position papers, and available to field questions from the press.

"Basically, both sides are pulling out all the stops," says Stephen C. Kaufman, one of Miss Lampshire's two attorneys, who has spent 15 months preparing for the trial.

The first task of Mr. Kaufman and his associate, John Kidneigh, is to prove that Miss Lampshire did indeed have toxic-shock syndrome. The disease, most commonly contracted by women during or near the onset of the menstrual periods, is characterized by sudden high fever, vomiting, diarrhea and a rapid drop in blood pressure. Most victims recover, but some, including Miss Lampshire, complain of lingering emotional trauma and mental impairment.

Before she got sick, Miss Lampshire was president of her high-school class. Her attorneys say she was outgoing, involved in extracurricular activities and a "B-plus" student. But since she got sick, they contend,

she has been depressed, suffered from memory lapses, has curtailed outside activities, and experiences emotional trauma during her menstrual period. Because of these troubles, they claim, her first report card from the University of Denver included a "B" in accounting and an "incomplete" in math (although she got A's and B's in liberal-arts courses.)

The fact that Miss Lampshire didn't die from her disease, as more than 80 toxic-shock victims did, makes attorneys for some other plaintiffs wish hers wasn't the first



P&G is expected to send in scientific experts who will say the evidence against Rely is too weak. Attorneys for the other side say liability suits don't require proof as strict as that demanded by scientists.

P&G case to reach trial. They would have preferred a death case as a stronger precedent-setter, says one, but "had zero success" in getting Messrs. Kaufman and Kidneigh to postpone their case. Mr. Kidneigh counters that he can't "sit back because my client didn't die."

One of the star witnesses for the plaintiff will be Dr. Bruce Dan, a former official of the federal Center for Disease Control. A sharp critic of P&G, Dr. Dan is appearing as an expert witness for Messrs. Kaufman and Kidneigh (at a hefty \$3,000 a day, say other attorneys in the field).

Legal sources estimate that P&G has spent tens of millions of dollars preparing for this and subsequent Rely trials. The sum

includes work only indirectly related to litigation. The company has financed at least 14 major toxic-shock research projects by outside scientists, at a cost of about \$2 million. One of those projects, at the University of Wisconsin, has found that certain tampons induce a strain of bacteria present in the human body to produce a waste product widely suspected of causing toxic shock.

P&G won't comment on its courtroom strategy. The company will call as witnesses several former and current executives, including a former chairman, Edward G. Harness. The company also plans to send in a battalion of scientific experts who undoubtedly will contend that the evidence against Rely is too weak.

Product-liability experts suggest that the company will point out alternative explanations for toxic shock, and note that the illness is sometimes found in men, children and women who don't menstruate.

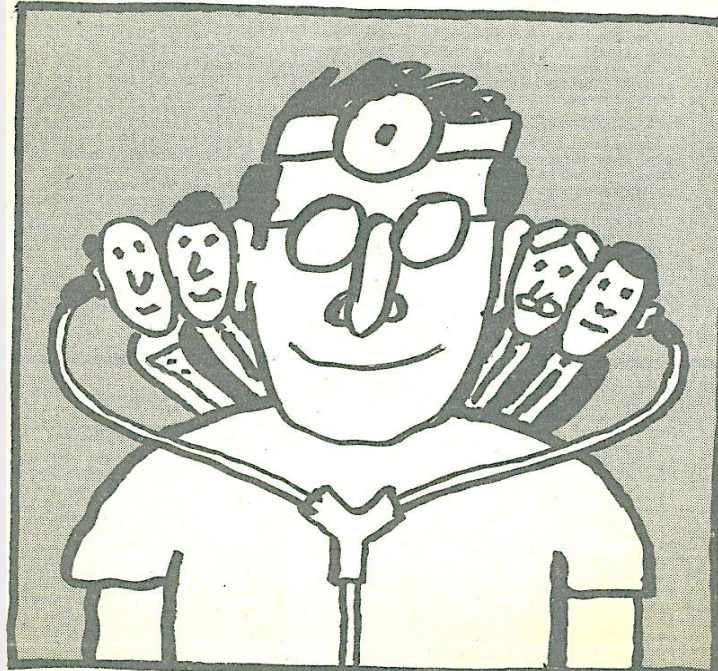
Sexual Inquiries

Perhaps a hint of what is in store for Miss Lampshire can be found in pretrial questioning in other P&G cases. In a New York case involving a 17-year-old toxic-shock victim, P&G's attorneys wanted to know if she had engaged in sexual intercourse within three months of her illness. When the girl and her attorneys refused to answer, the company got a court order requiring her to. She said no, and the company didn't pursue the point (it has suggested that such information could be relevant to determining whether the illness is toxic shock or something else.)

As for the plaintiff, Messrs. Kaufman and Kidneigh stress that they don't have to prove their case to a group of scientists, but to a jury of laymen and women. Mr. Kaufman says the legal definition of "cause" in product liability suits doesn't require proof as strict as that demanded by scientists. He says he will make the point that "but for the fact that the plaintiff used tampons, she wouldn't have taken ill."

Because of the high stakes, P&G's Cincinnati law firm—Dinsmore, Shohl, Coates & Deupree—has taken a particularly tough approach in pretrial proceedings. Messrs. Kaufman and Kidneigh say they have had to ask the court to compel P&G to turn over

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Stuart Goldenberg

How Much Privacy for Toxic Shock Victims?

By DAVID BURNHAM

WASHINGTON — The medical principle of confidentiality, a tenet of every physician's oath since Hippocrates, "has become old, worn-out and useless — a decrepit concept," according to Dr. Mark Siegler, a Chicago physician.

Writing in a recent issue of *The New England Journal of Medicine*, Dr. Siegler said he based his conclusion in part on his experiences in a teaching hospital where "at least 25 and perhaps as many as 100 health professionals and administrative personnel have access and a legitimate need to examine the records of a patient undergoing elective surgery."

In one case, these included 6 attending physicians (the primary physician, the surgeon, the pulmonary consultant and other specialists); 12 nurse officers (medical, surgical, intensive-care unit, "covering" staff); 20 nurses; 6 respiratory therapists; 3 nutritionists; 3 dietitians; 1

score of government and corporate employees who routinely examine medical records in preparing insurance payments.

Many people are horrified by the assertion that medical privacy is dead, believing that the delicate relationship between doctor and patient thought essential to the practice of medicine must surely be jeopardized. But in an age of computerized record keeping, which facilitates data transfer, and national insurance programs, which seek out intimate details concerning a patient's condition to substantiate claims, securing medical records from outside scrutiny seems impossible. And in an era of multidisciplinary medical teams, a doctor's refusal to share with health professionals a patient's history seems undesirable.

Almost daily, the principle of medical privacy comes under new assault. A few months ago the aggressor was Procter & Gamble Company, the manufacturer of Rely tampons, which had been linked to the incidence of toxic shock syndrome

Rely and toxic shock. The confirmation was necessary to its suits brought by victims, or times, of toxic shock.

Under provisions of the Freedom of Information Act, the Government inspected Procter & Gamble 34,000 pages concerning the studies. It was not the questions asked and the answers that not permit adequate evaluation, the company argued. "One must address and addresses of the interviewees, contact them (and assess) the effectiveness and recall bias on the rest of the study," Feinstein, a physician and epidemiologist, testified in the company's behalf.

Many doctors and lawyers were in Procter & Gamble's favor, saying that the right to discovery provisions of the Freedom of Information Act that protect citizens.

"Such a decision would pose a threat to a variety of important government information collection," Dr. Sydney Wolfe, who heads the Research Group, a Washington organization, Dr. Wolfe noted. Occupational Health and Safety efforts to collect complaints of violations in the work place. Under the act, those who report hazards are protected from harassment by a guarantee that their identity will be kept confidential.

The Regulations That

"Epidemiological studies of chloride and smoking are essential in understanding the hazards of modern life," Reingold, an epidemiologist at the Centers for Disease Control, said. "And they are dependent upon public confidence in the information provided by specific individuals."

Some health professionals believe that patient confidence must be protected. Lawmakers, however, seem reluctant. Congress recently defeated legislation that would have established privacy rules for those receiving Medicare and Medicaid. Under the proposal, patients would have seen and corrected their records before they were read. Hospitals would have been prohibited from sharing with outside parties data, such as the doctor's diagnosis, without patient consent.

The legislation failed in part because of opposition from the American Hospital Association, which called it another example of Federal overregulation. Representative Boland, Democrat of Massachusetts, said that a provision of the legislation that a psychiatrist might tell, without patient consent, intelligence agencies — would harm "the national security." He said the legislation was apparently suggesting that spies and security risks would be identified by psychiatrists did not flag possible risks.

Dr. Siegler contends that rather than restoring the myth of confidentiality, the medical profession would be weakened if they admitted the major intrusions and set about salvaging whatever remains. He suggested restoring the principle that doctors and nurses should not discuss patients while walking through the hospital. "I suspect that the prin-

758 F.2d 1545 (1985)

Richard A. FARNSWORTH, et al., Plaintiffs,
v.
The PROCTER & GAMBLE COMPANY, et al., Defendants/Appellants,
v.
CENTER FOR DISEASE CONTROL, Movant/Appellee.

No. 84-8330.

United States Court of Appeals, Eleventh Circuit.

April 29, 1985.

1546 *1546 Lawrence R. Elleman, Cincinnati, Ohio, Dan B. Wingate, Atlanta, Ga., for defendants, appellants.

Nina L. Hunt, Asst. U.S. Atty., Atlanta, Ga., for movant, appellee.

Before RONEY and HENDERSON, Circuit Judges, and TUTTLE, Senior Circuit Judge.

RONEY, Circuit Judge:

Procter and Gamble (P & G) appeals from a discovery protective order granted by the district court under Fed.R.Civ.P. 26(c) denying it access to the names and addresses of women who gave the Center for Disease Control (Center) personal information as participants in the Center's Toxic Shock Syndrome (TSS) studies. The sole issue on appeal is whether the order was within the district court's discretion. 101 F.R.D. 355. We affirm.

Plaintiffs filed product liability actions in United States District Courts in Massachusetts, Missouri, Washington, New Mexico, Wisconsin, Indiana and Tennessee, seeking to recover damages from Procter and Gamble for Toxic Shock Syndrome allegedly caused by "Rely" tampons manufactured by P & G. Because plaintiffs intended to introduce into evidence a certain Center study purportedly linking "Rely" tampons with TSS, P & G served the Center with a subpoena seeking to discover the names and addresses of women who participated in the study. P & G hoped to discredit the Center study by pointing out certain purported "biases" in the methodology, and asserts that it needs to personally contact each woman involved in the study to adequately detail those faults. The Center, a non-party resident in Georgia, then moved for the protective order granted by the District Court in the Northern District of Georgia.

It is undisputed that the information sought by P & G is of a highly personal nature. The questions answered for the study concerned medical histories, sexual practices, contraceptive methods, pregnancy histories, menstrual activity, tampon usage, and douching habits. Participants provided this information on a voluntary basis. While no guarantee of anonymity was given, the Center fears that disclosure of such potentially embarrassing information would inhibit future studies by causing the public to fear disclosure of personal information given to the Center.

Responding to earlier P & G discovery requests, the Center turned over approximately 34,000 TSS-related research documents. The Center apparently provided P & G with every piece of information regarding its TSS studies, with the exception of the names and addresses of the participants. The Center has indicated to P & G its willingness to update the

Menstrual Toxic Shock Syndrome & Tampons, 1980 (continued)

- Lesson Learned:
Be Resilient (you will be challenged, even attacked)

Effect of HIV Infection on Transmission of M. tuberculosis, Dominican Republic, 1994-95

- **Problem:**

Effect of HIV infection on likelihood of transmitting M. tuberculosis by patients with pulmonary TB unknown

- **Approach:**

Prospective cohort study of household contacts of HIV-positive and HIV-negative patients with pulmonary TB

Effect of HIV Infection on Transmission of M. tuberculosis, Dominican Republic, 1994-95

- Results:
HIV-positive patients with pulmonary TB significantly less likely to transmit M. tuberculosis to household contacts

Effect of HIV Infection on Transmission of M. tuberculosis, Dominican Republic, 1994-95

- Lancet Reviewer:

“A well conducted case control study of tuberculosis in HIV-infected individuals and its spread within households at risk.”

Effect of HIV Infection on Transmission of M. tuberculosis, Dominican Republic,

- Lesson Learned:
Be skeptical (that those who should understand epidemiologic concepts do)

Summary

- Using state-of-the-art methods is important
- A DAG will help guide your epidemiological research
- Great methods are not a substitute for a good question and can't do much to correct for flawed study design and implementation (e.g. selection and information bias)
- Even antiquated epidemiologists can, on occasion, teach something useful