


# Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

Our File No. 799

RULE REVIEW CHECKLIST

DATE RULE RECEIVED 3-26-82
DATE FOR REVIEW 4-5-82
DATE DUE 4-9-82

Adopted w/a hearing _____
Adopted w/o hearing ✓
Temporary rule _____

Approved 4-9-82 Disapproved _____ Returned to Agency 4-12-82

Resubmitted _____ Due _____
Approved _____ Disapproved _____ Returned to Agency _____

Date filed w/Secretary of State 4-12-82 Revisor approved _____ disapproved _____

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✓ Rule as Adopted

✓ Rule as Proposed

✓ Order Adopting 3.22.82 Date

N/A Notice of Intent to Solicit Outside Opinion

✓ Order for rulemaking
N/A date of Hearing

N/A Certificate of Board's Authorizing Resolution

✓ Notice of rulemaking
✓ Sufficiency

✓ Affidavit of Mailing Notice or rulemaking
12.31.81 At least 30 days prior to ~~hearing~~/adoption

✓ Mailing list Certificate

✓ Publication in State Register
1.11.82 At least 30/~~20~~ days prior to ~~hearing~~/adoption

N/A Hearing Examiner's Report

N/A Chief Hearing Examiner's Report(s)
_____ Approving H.E.'s Report
_____ Approving agency action

_____ Agency's Findings of Fact

_____ LCRAR Report or agency Affidavit

✓ Certificate of Board's Resolution Adopting Rules

✓ Order Approving Incorporation by Reference

✓ Statement of Need and Reasonableness

N/A Petition for Adoption of a Rule

N/A Record (includes transcript or tape, exhibits, comments received by agency, requests for a hearing, and other relevant materials)

✓ Certificate of Compliance w/Rulemaking Procedures

✓ Affidavit of Mailing Notice of Submission to Attorney General

N/A Notice of Submission to the Attorney General

STATE OF MINNESOTA

DEPARTMENT ATTORNEY GENERAL **Office Memorandum**

TO : GEORGE R. PETTERSEN, M.D.
Commissioner of Health

DATE: 4/9/82

ATTN : TERRY P. O'BRIEN, Spec. Ass't. Atty. Gen.

FROM : LARRY D. STARNS
Special Assistant
Attorney General

PHONE: 297-3493

SUBJECT: MHD 326(o) Relating to Prophylaxis for Opthalmia Neonatoram

Enclosed herewith are the rules you have submitted for approval. These rules have been approved by this office and filed with the Secretary of State. Please note that they have not been filed with the State Register. This must be done promptly by your agency.

Upon receipt and before transmittal to your agency, however, it is important that you recheck these rules as to:

1. Affixation of stamps of the Attorney General and Secretary of State;

2. Coverage by these stamps of all rules submitted; and

3. Inclusion of all pages to the rules in the approved set.

If you have any questions in this regard, please contact me.

LDS:drw
Encs.

cc: Ms. Kathy Burek
Mr. Duane Harves

STATE OF MINNESOTA
OFFICE OF THE ATTORNEY GENERAL
ST. PAUL 55155

WARREN SPANNAUS
ATTORNEY GENERAL

March 26, 1982

ADDRESS REPLY TO:
136 UNIVERSITY PARK PLAZA BLDG.
2829 UNIVERSITY AVENUE S.E.
MINNEAPOLIS, MN 55414
TELEPHONE: (612) 341-7272

Mr. Ted Martinez
Special Assistant
Attorney General
Administration Division
204 Administration Building
50 Sherburne Avenue
St. Paul, Minnesota 55155

Re: Proposed Amendments to Mn. Rule MHD 326(o)

Dear Mr. Martinez:

Pursuant to 1 MCAR § 1.203 please find enclosed for your review and approval:

1. Rule as Adopted (original and three copies. No changes were made in the rule from the form in which it was originally published in the State Register).

2. Order Adopting Rule (original and two copies).

3. Order for Notice of Intent to Adopt a Rule Without a Public Hearing.

4. Notice of Intent to Adopt a Rule Without a Public Hearing.

5. Affidavit of Mailing Notice of Intent to Adopt a Rule Without a Public Hearing.

6. Certificate of Mailing List.

7. Rule as Proposed (Revisor's approved copy and copy of State Register dated January 11, 1982).

8. Statement of Need and Reasonableness.

9. An Affidavit stating that no written comments on the rule or requests for a public hearing were received and no one requested Notice of Submission to the Attorney General.

10. Certificate of Compliance with Rulemaking Procedures.

Very truly yours,

TERRY P. O'BRIEN
Special Assistant
Attorney General

TPO:sd

Enclosures

Department of Health

Adopted Amendments to Rule Relating to Prophylaxis for Opthalmia Neonatoram

Rule as Adopted

MHD 326 Additional control measures for certain communicable diseases.

(o) Ophthalmia neonatorum.

(1) Definition. Any condition of the eye or eyes of an infant, independent of the nature of the infection, in which there is any inflammation, swelling, or redness in either one or both eyes of any such infant, either apart from, or together with, any unnatural discharge from the eye or eyes of any such infant within two weeks of the birth of such infant, shall be known as ophthalmia neonatorum.

(2) Prophylaxis. The licensed health professional in charge of the delivery at the time of the birth of any newborn infant shall instill or have instilled, within one hour of birth or as soon as possible thereafter, a one percent solution of silver nitrate, or tetracycline ointment or drops, or erythromycin ointment or drops.

(3) Treatment. A licensed health professional who is not a licensed physician but who is in charge of the care of a newborn infant shall immediately bring to the attention of a licensed physician every case in which symptoms of inflammation develop in one or both eyes of an infant in his or her care.

(4) Objections. If a parent objects or both parents object to the prophylactic treatment of a newborn infant and the health professional has honored the objection, the health professional shall retain a record of the objection.

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED
APR 12 1982
Joan Anderson Growe
Secretary of State
9:50 A.M

APPROVED AS TO LEGALITY
April 9, 1982
WARREN SPANNAUS, ATTORNEY GENERAL
BY Jerry D. Akers
SPECIAL ASSISTANT ATTORNEY GENERAL

Rule as Adopted

MHD 326 Additional control measures for certain communicable diseases.

(o) Ophthalmia neonatorum.

(1) Definition. Any condition of the eye or eyes of an infant, independent of the nature of the infection, in which there is any inflammation, swelling, or redness in either one or both eyes of any such infant, either apart from, or together with, any unnatural discharge from the eye or eyes of any such infant within two weeks of the birth of such infant, shall be known as ophthalmia neonatorum.

(2) ~~Treatment of eyes--duties of physicians, midwives and others. It shall be the duty of any physician or midwife in attendance on, or in charge of, a confinement case to treat the eyes of every newborn babe with a 1 per cent solution of silver nitrate.~~ Prophylaxis. The licensed health professional in charge of the delivery at the time of the birth of any newborn infant shall instill or have instilled, within one hour of birth or as soon as possible thereafter, a one percent solution of silver nitrate, or tetracycline ointment or drops, or erythromycin ointment or drops.

~~(3) It shall be the duty of any midwife immediately to call a licensed physician in every case in which symptoms of inflammation develop in one or both eyes of infants under her care.~~ Treatment. A licensed health professional who is not a licensed physician but who is in charge of the care of a newborn infant shall immediately bring to the attention of a licensed physician every case in which symptoms of inflammation develop in one or both eyes of an infant in his or her care.

~~(4) It shall be the duty of any physician, surgeon, obstetrician, midwife, nurse, maternity home, or hospital of any nature, parent, relative, and any person or persons attendant on, or assisting in any way whatsoever, any woman at childbirth, or attendant on, or assisting in any way whatsoever, any infant, or the mother of any infant, at any time within two weeks after childbirth, knowing the condition hereinabove defined to exist,~~

~~and within eight hours thereafter, to report such fact, as the State Board of Health shall direct, to the local health officer of the city, village or township within which the infant is cared for.~~

~~(5) Duties of maternity homes, physicians, etc. It shall be the duty of all maternity homes and of hospitals, public and charitable institutions to maintain such records of cases of ophthalmia neonatorum as the State Board of Health shall direct. It shall be the duty of any and all maternity homes, hospitals, public and charitable institutions, and all other institutions having the care of any infant, in addition to reporting as hereinbefore provided, to employ a licensed physician in the treatment of the conditions described in Regulation MHD 326(c)1.~~

~~(6) Duties of the local health officer. It shall be the duty of the local health officer:~~

~~(aa) To investigate each case as filed with him in pursuance with the law, and any other such case as may come to his attention.~~

~~(bb) To report all cases of ophthalmia neonatorum, and the result of all such investigations as he shall make, as the State Board of Health shall direct.~~

~~(cc) To conform to such other rules and regulations as the State Board of Health shall promulgate for his further guidance.~~

Objections. If a parent objects or both parents object to the prophylactic treatment of a newborn infant and the health professional has honored the objection, the health professional shall retain a record of the objection.

Rule as Proposed

MHD 326 Additional control measures for certain communicable diseases.

(o) Ophthalmia neonatorum.

(1) Definition. Any condition of the eye or eyes of an infant, independent of the nature of the infection, in which there is any inflammation, swelling, or redness in either one or both eyes of any such infant, either apart from, or together with, any unnatural discharge from the eye or eyes of any such infant within two weeks of the birth of such infant, shall be known as ophthalmia neonatorum.

~~(2) Treatment of eyes--duties of physicians, midwives and others. It shall be the duty of any physician or midwife in attendance on, or in charge of, a confinement case to treat the eyes of every newborn babe with a 1 per cent solution of silver nitrate.~~ Prophylaxis. The licensed health professional in charge of the delivery at the time of the birth of any newborn infant shall instill or have instilled, within one hour of birth or as soon as possible thereafter, a one percent solution of silver nitrate, or tetracycline ointment or drops, or erythromycin ointment or drops.

~~(3) It shall be the duty of any midwife immediately to call a licensed physician in every case in which symptoms of inflammation develop in one or both eyes of infants under her care.~~ Treatment. A licensed health professional who is not a licensed physician but who is in charge of the care of a newborn infant shall immediately bring to the attention of a licensed physician every case in which symptoms of inflammation develop in one or both eyes of an infant in his or her care.

~~(4) It shall be the duty of any physician, surgeon, obstetrician, midwife, nurse, maternity home, or hospital of any nature, parent, relative, and any person or persons attendant on, or assisting in any way whatsoever, any woman at childbirth, or attendant on, or assisting in any way whatsoever, any infant, or the mother of any infant, at any time within two weeks after childbirth, knowing the condition hereinabove defined to exist,~~



APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

~~and within eight hours thereafter, to report such fact, as the State Board of Health shall direct, to the local health officer of the city, village or township within which the infant is cared for.~~

~~(5) Duties of maternity homes, physicians, etc. It shall be the duty of all maternity homes and of hospitals, public and charitable institutions to maintain such records of cases of ophthalmia neonatorum as the State Board of Health shall direct. It shall be the duty of any and all maternity homes, hospitals, public and charitable institutions, and all other institutions having the care of any infant, in addition to reporting as hereinbefore provided, to employ a licensed physician in the treatment of the conditions described in Regulation MHD 326(e)1.~~

~~(6) Duties of the local health officer. It shall be the duty of the local health officer:~~

~~(aa) To investigate each case as filed with him in pursuance with the law, and any other such case as may come to his attention.~~

~~(bb) To report all cases of ophthalmia neonatorum, and the result of all such investigations as he shall make, as the State Board of Health shall direct.~~

~~(cc) To conform to such other rules and regulations as the State Board of Health shall promulgate for his further guidance.~~

Objections. If a parent objects or both parents object to the prophylactic treatment of a newborn infant and the health professional has honored the objection, the health professional shall retain a record of the objection.



APPROVED IN THE REVISOR OF STATUTES OFFICE BY:

12/01/81
RD131

OFFICE OF THE REVISOR OF STATUTES
PROPOSED RULES

Agency Department of Health

Division Disease Prevention and Control

Agency Contact Michael Moen Phone Number 296-5589

Title: Proposed Rules Governing Treatment of Certain Eye Conditions of Newborn Infants.

Type of Rules: Permanent X Temporary_____

Incorporations by References: None

| Rule Number | Material Incorporated |
|---|---|
| | Author |
| | Title |
| | Place |
| | Publisher |
| | Date |
| | Cost |
| | Places Available |

See Additional references on back Yes___ No___

Duplication of Statutory Language None

| Rule Number | Statutory Section Duplicated |
|---|---|

The attached rules are approved as to form.

Steven C. Cross
Revisor of Statutes

12-1-81

Name: Theresa M. Lauterbach

Theresa M. Lauterbach

Title: Assistant Revisor

Phone: 296-0956

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the
Proposed Amendments
to Mn. Rule MHD 326(o)
Relating to Prophylaxis
for Opthalmia Neonatoram

ORDER ADOPTING RULE

Notice of the Commissioner of Health's intent to adopt the above-entitled rule without a public hearing was published in the State Register on January 11, 1982, and was sent by the United States mail to all persons on the list maintained by the Minnesota Department of Health pursuant to Minn. Stat. § 15.0412, subd. 4 on December 31, 1981. After affording interested and affected persons an opportunity to submit comments for 30 days after Notice, receiving no requests for a public hearing within the 30-day comment period, and determining the need for and reasonableness of the above-captioned rules,

NOW, THEREFORE, IT IS ORDERED that the rule identified as Mn. Rule MHD 326(o) is adopted this 22 day of March, 1982, pursuant to authority vested in me by Minnesota Statutes.

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

George R. Petterson M.D.

GEORGE R. PETTERSEN, M.D.
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the
Proposed Amendments
to 7 MCAR § 1.326(o)
Relating to Prophylaxis for
Opthalmia Neonatoram

ORDER FOR NOTICE OF
INTENT TO ADOPT RULES
WITHOUT PUBLIC HEARING

IT IS ORDERED this 24th day of December, 1981, that Notice of Intent to Adopt Rules Without a Public Hearing in the above-entitled matter be published in the State Register and be given to all persons who have registered their names with the Minnesota Department of Health for that purpose.

STATE OF MINNESOTA

COMMISSIONER OF HEALTH

George R. Petersen M D

GEORGE R. PETTERSEN, MD
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the
Proposed Amendments
to 7 MCAR § 1.326(o)
Relating to Prophylaxis for
Opthalmia Neonatoram

NOTICE OF INTENT TO
ADOPT RULES WITHOUT
A PUBLIC HEARING

NOTICE IS HEREBY GIVEN that the Commissioner of Health (hereinafter "Commissioner") proposes to amend 7 MCAR § 1.326(o). A copy of the proposed amendments is attached to this Notice. 10

The Commissioner has determined that these proposed amendments will be noncontroversial in nature. Therefore, this proceeding is being followed under the provision of Minn. Stat. § 15.0412, subd. 4h (Supp. 1981) which provides for an expedited process for the adoption of noncontroverted administrative rule changes without the holding of a public hearing. 2

THE PUBLIC IS HEREBY ADVISED that:

1. There is a 30-day period in which to submit comment on the proposed rule; 3

2. No public hearing will be held on this matter unless seven or more persons make a written request for a hearing within the 30-day comment period; 5

3. All comments and any written requests for a public hearing shall be submitted to David Brownell, State Venereal Disease Control Officer, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440; 6

4. The proposed amendments may be modified if modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language; 4

5. Authority to amend 7 MCAR § 1.326(o) is contained in Minn. Stat. § 144.12 (1980). Additionally, a Statement of Need and Reasonableness that 9

describes the need for and reasonableness of each provision of the proposed amendments has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Mr. Brownell at the above-listed address;

6. Under this expedited procedure, the agency must submit any action on its rules to the Attorney General for review of the form and legality of the rule change. Notice of the submission of this matter to the Attorney General will be made to all persons who request to be informed of the submission. Requests to be informed must be submitted to Mr. Brownell at the above-listed address;

7. If seven or more persons request a public hearing on this matter, notice of any such hearing will be given in the same manner as has this Notice, and the agency will then proceed pursuant to Minn. Stat.§ 15.0412, subds. 4–4g;

8. Any rule change made pursuant to this proceeding shall be effective five days after publication in the State Register of notice of the adoption of the change.

Dated: December 24, 1981

STATE OF MINNESOTA

DEPARTMENT OF HEALTH

George R. Petterson MD

GEORGE R. PETTERSEN, M.D.
Commissioner of Health

STATE OF MINNESOTA )
) ss.
COUNTY OF HENNEPIN )

In the Matter of the
Proposed Amendments
to Mn. Rule MHD 326(o)
Relating to Prophylaxis
for Opthalmia Neonatoram

AFFIDAVIT OF MAILING

Dave Brownell, being first duly sworn, deposes and says:

That on the 31st day of December, 1981, at the City of Minneapolis, County of Hennepin, State of Minnesota, he served the attached Notice of Hearing by depositing in the United States mail at said City of Minneapolis, a true and correct copy thereof, properly enveloped, with postage prepaid, to all persons and associations who have requested that their names be placed on file with the Minnesota Department of Health for the purpose of receiving notice of the proposed adoption of rules by the Commissioner of Health.

David F. Brownell

Subscribed and sworn to before me
this 22 day of March, 1982.

Frederick L. King

FREDERICK L. KING
WASHINGTON COUNTY
NOTARY PUBLIC-MINNESOTA
MY COMMISSION EXPIRES FEB. 22, 1984

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the
Proposed Amendments
to Mn. Rule MHD 326(o)
Relating to Prophylaxis
for Opthalmia Neonatoram

CERTIFICATE OF
MAILING LIST

I hereby certify that the list of persons, associations, and other interested groups who have requested, pursuant to Minn. Stat. § 15.0412, subd. 4, that their names be placed on file with and maintained by the Minnesota Department of Health for the purpose of receiving notice of the proposed adoption of rules by this agency is accurate and complete as of 9:00 AM, this 31st day of December, 1981.

George R. Petersen M.D.

GEORGE R. PETTERSEN, M.D.
Commissioner of Health

Michael J. Ahern
Moss, Flaherty, Clarkson & Fletcher
2350 IDS Center
Minneapolis, Minnesota 55402

Albert Lea Health Department
221 E. Clark
Albert Lea, Minnesota 56007

Sue Aldean-Linder, Exec. Dir.
Ramsey County Medical Society
908 American National Bank Building
101 East 5th Street
St. Paul, Minnesota 55101

John H. Allers
7501 2nd Avenue South
Richfield, Minnesota 55423

Alternatives for Autistic People, Inc.
3725 - 47th Ave. So.
Minneapolis, Minnesota 55406

American Lung Association
Barbara L. Hughes
1829 Portland Ave. S.
Minneapolis, Minnesota 55404

Anderson Drilling, Inc.
4163 Seville Road
Duluth, Minnesota 55811

Alice Anderson
175 So Western
St. Paul, Minnesota 55102

Curtis Anderson, Supervising San.
St. Louis Co. Health Department
910 South 8½ Street
Virginia, Minnesota 55792

Donna M. Anderson
Community Health Services
Dakota County Government Center
1560 Highway 55
Hastings, Minnesota 55033

Herbert Anderson
418 8th St. So.
Virginia, Minnesota 55792

Ray C. Anderson
Minnesota-Dakotas Retail Hardware Assoc.
3033 Excelsior Boulevard
Minneapolis, Minnesota 55416

Allyson Ashley, ACSW
Executive Director
Southwestern Mental Health Center
2 Round Wind Road
Luverne, Minnesota 56156

Association of Residences for
the Retarded in Minnesota
459 Rice Street, Suite 301
St. Paul, Minnesota 55103

Sister Margaret Belanger
Saint Joseph's Hospital
69 West Exchange Street
St. Paul, Minnesota 55102

Beverly Balos
Family & Childrens Service
414 South Eighth Street
Minneapolis, Minnesota 55404

Bonnie Bannanno
Room 300
1745 University Avenue
St. Paul, Minnesota 55104

R. J. Barto
Midland Glass Company, Inc.
P.O. Box 69
Shakopee, Minnesota 55379

Thomas W. Bastien
1409 Willow Street
Minneapolis, Minnesota 55403

Dean Beaulieu
5th Street and Portland Ave. So.
Minneapolis, Minnesota 55415

Joseph R. Begich
100 North 2nd Street
Eveleth, Minnesota 55734

Benes Well Drilling
2214 - 5th Street N.W.
Grand Rapids, Minnesota 55744

John R. Benitez
4704 Harlan Street - 6th Floor
Denver, Colorado 80212

Jayne Berg
New Connection Prog., Inc.
73 Leech Street
St. Paul, Minnesota 55102

Bergerson Caswell
5115 Industrial Street
Maple Plain, Minnesota 55359

Berkeley Pump Co.
P.O. Box 32151
Minneapolis, Minnesota 55432

Betts Well Drilling
Route 1 Box 97
Sandstone, Minnesota 55072

James Biggar
205 West Center
Lake City, Minnesota 55041

Bonnie Bilinsky, RS
License and Inspection Department
14600 Minnetonka Boulevard
Minnetonka, Minnesota 55343

Bisson's Well & Pump Company
1955 Shawnee Road
St. Paul, Minnesota 55122

Gerald T. Blaha
457 Goodhue Street
St. Paul, Minnesota 55102

Board of Dentistry
717 S.E. Delaware Suite 338
Minneapolis, Minnesota 55414

Wendy M. Borsheim
Minnesota Retail Merchants Association
180 Metro Square Bldg.
St. Paul, Minnesota 55101

Christine E. Boswell
Assoc. Dir., MARC
2344 Nicollet Ave. So.
Minneapolis, Minnesota 55404

Burdette Boyum
250 So. 4th St., Room 300
Minneapolis, Minnesota 55415

Chester Bradseth
Blackduck Box 35
Blackduck, Minnesota 56630

Philip D. Brick
Pickands Mather & Company
Suite 811 - 202 West Superior Street
Duluth, Minnesota 55802

Briggs & Morgan
Librarian
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St. Paul, Minnesota 55101

John M. Broeker
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Minneapolis, Minnesota 55420

Richard C. Buske
Minnesota Department of Economic
Development
480 Cedar St.
St. Paul, Minnesota 55101

Cannon Well Drilling, Inc.
Route #1, Box 266A
Cannon Falls, Minnesota 55009

Rick Carter
Minnesota Association of Health
Care Facilities
2850 Metro Drive, #429
Minneapolis, Minnesota 55420

Caio G. Cesolini
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Shooks Rt. Box 27
Northome, Minnesota 56661

Philip M. Chen
Dorsey, Windhorst, Hannaford, Whitney
& Halladay
2300 First National Bank Building
Minneapolis, Minnesota 55402

Chiropractors Association of Minnesota
1803 Wood Lane Drive
Woodbury, Minnesota 55125

Fredrik M. Christiansen
Room 911, Capitol Square Building
St. Paul, Minnesota 55101

Philip J. Clausen
2307 Standish St.
St. Paul, Minnesota 55108

William Conley
Mental Health Association of Minnesota
6715 Minnetonka Boulevard
Minneapolis, Minnesota 55426

Director - Office of Consumer Services
128 Metro Square
7th & Robert
St. Paul, Minnesota 55101

Rodney L. Danielson
Carpenters Union #87
411 Main
St. Paul, Minnesota 55102

City of Rosemount
Don F. Darling, Clerk
P.O. Box 455
Rosemount, Minnesota 55068

Jean Dawson, Editor
The Minnesota Government Report
B-12 Press Room - Capitol
St. Paul, Minnesota 55155

Donald A. Dee, Executive Director
Minnesota State Pharmaceutical Association
2469 University Ave.
St. Paul, Minnesota 55114

Mr. Rollin Dennistoun
Deputy Commissioner
Department of Agriculture
90 W. Plato Boulevard
St. Paul, Minnesota 55107

Janice M. Devens
Director
Human Service Agency
Wright County Courthouse
Buffalo, Minnesota 55313

Ben M. Determan
Decatur Pump Company
P.O. Box 431
Decatur, Illinois 62525

Developmental Disabilities Planning
Office Director
200 Capitol Square Building
St. Paul, Minnesota 55101

Ron DeHollander
1600 Ute Avenue
Grand Junction, Colorado 81501

John Dlugosch
Thoele Dental Lab
Box 928
St. Cloud, Minnesota 56301

Dawn Donsmone
Mental Health Advanced Coalition
265 Fort Road
St. Paul, Minnesota 55102

Donahauer Well & Pump Company
R.R. 2
St. Joseph, Minnesota 56374

John E. Drawz
LeFevere, Lefler, Kennedy, O'Brien & Drawz
1100 First National Bank Building
Minneapolis, Minnesota 55402

Department of Ecology, Licensing of
Well Drillers
Olympia, Washington 98504

Edina Health Department
4801 N. 50th St.
Edina, Minnesota 55424

Kent E. Eklund
Minnesota Department of Economic
Development
480 Cedar St.
St. Paul, Minnesota 55101

Energy Reserves Group, Inc.
Attention: R. F. Hemming
1536 Cole Boulevard
Golden, Colorado 80401

Environmental Law Society
William Mitchel College of Law
875 Summit Avenue
St. Paul, Minnesota 55105

Glenn A. Erickson
445 City Hall
St. Paul, Minnesota 55102

Jack V. Everett - Consul. Geologist
10151 North Shore Drive
Duluth, Minnesota 55804

Department of Environmental Resources
Division of Water Supplies
Paul S. Zimmerman
P. O. Box 2357
Harrisburg, Pennsylvania 17120

John T. Farmer
Minnesota Manufactured Housing Association
222 E. Little Canada Road
Little Canada, Minnesota 55117

Paul Farseth
11691 Lausing Ave. N.
Stillwater, Minnesota 55082

Roberto M. Federigan, Senior Analyst
State Information Unit -- Room 650
The Bureau of National Affairs, Inc.
1231 25th Street, N.W.
Washington, D.C. 20037

Richard S. Felhaber
W-1080 First National Bank Building
St. Paul, Minnesota 55101

John W. Ferman
Minnesota Pollution Control Agency
1935 W. County Road B-2
Roseville, Minnesota 55113

Sara Ferris/Cystic Fibrosis Foundation
2344 Nicollet, Suite 330
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Marylee Fithian
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Bob Fitzgerald
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Miller A. Friesen
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Duluth, Minnesota 55802

Nelson French
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Minneapolis, Minnesota 55406

R. Gary Freund
St. Joseph's Hospital
Pharmacy Department
69 W. Exchange Street
St. Paul, Minnesota 55102

Charles A. Geer
Dorsey, Windhorst, Hannaford, Whitney
& Halladay
2300 First National Bank
Minneapolis, Minnesota 55402

General Mills, Inc.
Attn: J. W. Haun
P.O. Box 1113
Minneapolis, Minnesota 55440

Marvin Giza
115 North 5th
Staples, Minnesota 56479

Betsy Glassman
304½ Carlton Avenue
Cloquet, Minnesota 55720

John B. Gordon
1300 Northwestern Bank Building
Minneapolis, Minnesota 55402

Government Center Library
C-2359 Government Center
300 South 6th Street
Minneapolis, Minnesota 55487

Ella Grass
1001 Penn North
Minneapolis, Minnesota 55411

Phil Graves
Hospital Administrator
Century Avenue
Hutchinson, Minnesota 55350

Katherine Gray
Ebenezer Center for Aging
2722 Park Avenue South
Minneapolis, Minnesota 55407

Lynn R. Gruber
Minnesota Medical Assoc.
Suite 400 Health Assoc. Center
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Minneapolis, Minnesota 55414

Bruce Gunderson
Box 16 B Star Route
Karlstad, Minnesota 56732

William G. Haddeland
Minnesota Petroleum Council
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St. Paul, Minnesota 55102

Raymond A. Haik
4344 IDS Center
Minneapolis, Minnesota 55402

Public Law Research Center
Hamline University School of Law
1536 Hewitt Avenue
St. Paul, Minnesota 55104

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# PROPOSED RULES

Pursuant to Minn. Laws of 1980, § 15.0412, subd. 4h, an agency may propose to adopt, amend, suspend or repeal rules without first holding a public hearing, as long as the agency determines that the rules will be noncontroversial in nature. The agency must first publish a notice of intent to adopt rules without a public hearing, together with the proposed rules, in the *State Register*. The notice must advise the public:

1. that they have 30 days in which to submit comment on the proposed rules;
2. that no public hearing will be held unless seven or more persons make a written request for a hearing within the 30-day comment period;
3. of the manner in which persons shall request a hearing on the proposed rules;

and

4. that the rule may be modified if modifications are supported by the data and views submitted.

If, during the 30-day comment period, seven or more persons submit to the agency a written request for a hearing of the proposed rules, the agency must proceed under the provisions of § 15.0412, subds. 4 through 4g, which state that if an agency decides to hold a public hearing, it must publish in the *State Register* a notice of its intent to do so. This notice must appear at least 30 days prior to the date set for the hearing, along with the full text of the proposed rules. (If the agency has followed the provisions of subd. 4h and has already published the proposed rules, a citation to the prior publication may be substituted for republication.)

Pursuant to Minn. Stat. § 15.0412, subd. 5, when a statute, federal law or court order to adopt, suspend or repeal a rule does not allow time for the usual rulemaking process, temporary rules may be proposed. Proposed temporary rules are published in the *State Register*, and for at least 20 days thereafter, interested persons may submit data and views in writing to the proposing agency.

## Department of Health

### Proposed Amendments to Rule Relating to Prophylaxis for Opthalmia Neonatoram

#### Notice of Intent to Adopt Rules without a Public Hearing

Notice is hereby given that the Commissioner of Health (hereinafter "commissioner") proposes to amend MHD 326. A copy of the proposed amendments is attached to this notice.

The commissioner has determined that these proposed amendments will be noncontroversial in nature. Therefore, this proceeding is being followed under the provision of Minn. Stat. § 15.0412, subd. 4h (Supp. 1981) which provides for an expedited process for the adoption of noncontroverted administrative rule changes without the holding of a public hearing.

The public is hereby advised that:

1. There is a 30-day period in which to submit comment on the proposed rule;

2. No public hearing will be held on this matter unless seven or more persons make a written request for a hearing within the 30-day comment period;

3. All comments and any written requests for a public hearing shall be submitted to David Brownell, State Venereal Disease Control Officer, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440;

4. The proposed amendments may be modified if modifications are supported by the data and views submitted and do not result in a substantial change in the proposed language;

5. Authority to amend MHD 326 is contained in Minn. Stat. § 144.12 (1980). Additionally, a statement of need and reasonableness that describes the need for and reasonableness of each provision of the proposed amendments has been prepared and is now available. Anyone wishing to receive a copy of this document may contact Mr. Brownell at the above-listed address;

6. Under this expedited procedure, the agency must submit any action on its rules to the Attorney General for review of the form and legality of the rule change. Notice of the submission of this matter to the Attorney General will be made to all persons who request to be informed of the submission. Requests to be informed must be submitted to Mr. Brownell at the above-listed address;

7. If seven or more persons request a public hearing on this matter, notice of any such hearing will be given in the same manner as has this notice, and the agency will then proceed pursuant to Minn. Stat. § 15.0412, subds. 4-4g;

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike~~ ~~outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." ADOPTED RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike~~ ~~outs~~ indicate deletions from proposed rule language.

8. Any rule change made pursuant to this proceeding shall be effective five days after publication in the *State Register* of notice of the adoption of the change.

December 24, 1981

George R. Pettersen, M.D.
Commissioner of Health

## Rule as Proposed

**MHD 326 Additional control measures for certain communicable diseases.**

(o) Ophthalmia neonatorum.

(1) Definition. Any condition of the eye or eyes of an infant, independent of the nature of the infection, in which there is any inflammation, swelling, or redness in either one or both eyes of any such infant, either apart from, or together with, any unnatural discharge from the eye or eyes of any such infant within two weeks of the birth of such infant, shall be known as ophthalmia neonatorum.

(2) ~~Treatment of eyes—duties of physicians, midwives and others. It shall be the duty of any physician or midwife in attendance on, or in charge of, a confinement case to treat the eyes of every newborn babe with a 1 per cent solution of silver nitrate.~~ Prophylaxis. The licensed health professional in charge of the delivery at the time of the birth of any newborn infant shall instill or have instilled, within one hour of birth or as soon as possible thereafter, a one percent solution of silver nitrate, or tetracycline ointment or drops, or erythromycin ointment or drops.

(3) ~~It shall be the duty of any midwife immediately to call a licensed physician in every case in which symptoms of inflammation develop in one or both eyes of infants under her ear.~~ Treatment. A licensed health professional who is not a licensed physician but who is in charge of the care of a newborn infant shall immediately bring to the attention of a licensed physician every case in which symptoms of inflammation develop in one or both eyes of an infant in his or her care.

(4) ~~It shall be the duty of any physician, surgeon, obstetrician, midwife, nurse, maternity home, or hospital of any nature, parent, relative, and any person or persons attendant on, or assisting in any way whatsoever, any woman at childbirth, or attendant on, or assisting in any way whatsoever, any infant, or the mother of any infant, at any time within two weeks after childbirth, knowing the condition hereinabove defined to exist, and within eight hours thereafter, to report such fact, as the State Board of Health shall direct, to the local health officer of the city, village or township within which the infant is cared for.~~

~~(5) Duties of maternity homes, physicians, etc. It shall be the duty of all maternity homes and of hospitals, public and charitable institutions to maintain such records of cases of ophthalmia neonatorum as the State Board of Health shall direct. It shall be the duty of any and all maternity homes, hospitals, public and charitable institutions, and all other institutions having the care of any infant, in addition to reporting as hereinbefore provided, to employ a licensed physician in the treatment of the conditions described in Regulation MHD 326(o)1.~~

~~(6) Duties of the local health officer. It shall be the duty of the local health officer.~~

~~(aa) To investigate each case as filed with him in pursuance with the law, and any other such case as may come to his attention.~~

~~(bb) To report all cases of ophthalmia neonatorum, and the result of all such investigations as he shall make, as the State Board of Health shall direct.~~

~~(cc) To conform to such other rules and regulations as the State Board of Health shall promulgate for his further guidance.~~

Objections. If a parent objects or both parents object to the prophylactic treatment of a newborn infant and the health professional has honored the objection, the health professional shall retain a record of the objection.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the Proposed
Amendments to MHD 326(o)

STATEMENT OF NEED
AND REASONABLENESS

This rule is necessary for the prevention of infant blindness due to gonococcal infection. The attached reports indicate that silver nitrate in a 1 percent solution prevents 98% of newborns at risk of infection from developing gonococcal ophthalmia neonatorum. This proposal will continue to insure this high level of prevention while facilitating the inclusion of newer and more effective antibiotics in the prophylactic regimens authorized by the Commissioner.

As a result of recent information linking another organism, chlamydia, to ophthalmia neonatorum,[1,2] the Centers for Disease Control and the American Academy of Pediatrics have revised their recommendations for prevention of ophthalmia neonatorum to include tetracycline and erythromycin ointments or drops.[3]

Gonorrhea remains the most common reportable communicable disease in Minnesota. In calendar year 1980, 3400 new infections were reported in Minnesota women. Of this total 91% occurred in women of childbearing age (under 35). According to the statement of the American Academy of Pediatrics Committee on Drugs, Committee on Fetus and Newborn, Committee of Infectious Diseases "The prevalence of largely asymptomatic genital gonococcal infections in pregnant women and the occurrence of gonococcal ophthalmia neonatorum (estimated at 28%) born to infected women indicate the need for continued prophylaxis for all newborn infants."[4] According to the Centers for Disease Control, "silver nitrate prophylaxis reduced the risk of infants developing gonococcal ophthalmia neonatorum to less than 2%".[5]

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[1]Alexander ER: Chlamydia: The Organism and Neonatal Infection, Hospital Practice July, 1979, Attached hereto and made a part hereof in Attachment #1.

[2]Frommel GT, et al: Chlamydial infection of mothers and their infants., the Journal of Pediatrics, Vol. 95, No.1, July, 1979, Attached hereto and made a part hereof in Attachment #2.

[3]GONORRHEA Center for Disease Control Recommended Treatment Schedules 1979, Attached hereto and made a part hereof in Attachment #3.

[4]American Academy of Pediatrics, Committee on Drugs, Committee on Fetus and Newborn, Committee on Infectious Diseases: Prophylaxis and Treatment of Neonatal Gonococcal Infections, PEDIATRICS Vol.65, No.5, May,1980, Attached hereto and made a part hereof in Attachment #4.

[5]MMWR 27:107, 1978, Attached hereto and made a part hereof in Attachment #5.

The existing rule is too specific in requiring silver nitrate prophylaxis when the tetracycline or erythromycin regimens are recommended. In this proposal the Commissioner updates the recommended prophylactic treatment according to recommendations by the Centers for Disease Control and the American Academy of Pediatrics.

Paragraph (2) of the proposed rule is revised to reflect the reality that health professionals in addition to licensed physicians, nurses and midwives are involved in the delivery of newborn babies. The intent in this proposal is to be more inclusive and reflect the reality of modern practices.

Paragraph (3) of the proposed rule is revised to reflect the reality that health professionals in addition to licensed physicians, nurses and midwives provide care for newborn babies. The present rule requires only the "midwife to call a licensed physician when infection or inflammation is apparent". In reality nurses and other licensed health professionals are providing medical care for newborn babies and must also be responsible for notifying a licensed physician when these infections are observed in newborn infants under their care.

The basis for recommending deletion of all of paragraph (4) is that this requirement is unreasonable. Including "any and all persons", "any relative", etc. is so general that it would be difficult to identify any individual as a person in charge. Furthermore, requiring reporting of all cases of infection of eyes would needlessly overwhelm the state and local health officials. Such reports may include merely redness of the eyes, or a discharge from the eyes. Rigid compliance of the reporting requirements under this old rule would result in thousands of cases reported each year. There is no feasible action the State Health Department can take to prevent transmission to others of such infections. It is essential that a specific causative organism or agent be identified so that treatment and preventive measures can be taken.

With the exception of the portion of paragraph (5) requiring the keeping of records of cases the revision proposes the repeal of the remainder of this rule. The basis for this repeal being that it is unreasonable to make demands of institutions which might be budgetarily prohibitive. Prompt notification of a licensed physician, and assurance of treatment of cases as covered in other paragraphs adequately covers the intentions of the old rule.

Paragraph (6) and subparagraphs are repetitious. MHD 316 adequately covers reporting of communicable diseases. The proposed revision repeals MHD 316(o)(6) because it is unclear as to its meaning. If it refers to the reporting of gonorrhea, it is already addressed in MHD 326(n) and is therefore repetitious and unnecessary.

The Commissioner has chosed to initiate this revision under the provisions of Minn. Stat. §15.0412, Subd. 4(h) (Supp.1981). Under this provision, no public hearing will be required unless such is requested in writing by seven persons. Given the unclear mandate of the Legislature and the demonstrated need for revision of this rule, it is anticipated that this rule will be uncontroversial and that no hearing will be necessary.

Dated 12/24/81

STATE OF MINNESOTA
MINNESOTA DEPARTMENT OF HEALTH

David F. Brownell

David F. Brownell, Chief
Venereal Disease Control Program

# Chlamydia: The Organism and Neonatal Infection

E. RUSSELL ALEXANDER *University of Washington, Seattle*

Once believed to be large viruses, the causative agents of trachoma, psittacosis, inclusion conjunctivitis, and venereally transmitted genital tract infections have been reclassified as bacteria and placed in their own order, Chlamydiales. These organisms also can cause eye and respiratory infections in infants born to mothers with genital tract infection. Diagnosis, therapy, and prevention of such infections are described.

Several recent studies indicate that a high percentage of infants born to mothers with genital tract chlamydial infections become infected at birth and subsequently develop inclusion conjunctivitis or respiratory tract infection, or both. Since chlamydiae are estimated to cause between 30% and 40% of nongonococcal urethritis and cervicitis in this country, and since an average of 8% of pregnant women carry chlamydiae in their cervices at parturition, the risk of neonatal infection constitutes a major public health problem.

The chlamydial organisms cause trachoma, psittacosis, and lymphogranuloma venereum, as well as venereally transmitted genital tract infections and inclusion conjunctivitis. Over the years they have been called by a number of different names, including Bedsonia, Miyagawanella, and TRIC agents, the latter an acronym for the subset that causes trachoma-inclusion conjunctivitis. Chlamydiae are notable for being on the borderline between viruses and bacteria. For many years they were classified as viruses. Now it is clear that they are in fact bacteria, but because of their peculiar life cycle they have been placed in their own order, which consists of one genus, Chlamydia, with two species, *Chlamydia psittaci* and *Chlamydia trachomatis*.

Although chlamydiae share with viruses the trait of being obligate intracellular parasites, by definition this is true only in the intracellular stage of their life cycle, which begins extracellularly. The extracellular form of the organism is the elementary body, and it alone is infectious. Attaching to a host cell, the elementary body induces active phagocytosis and is ingested in a vesicle that becomes the setting for the next stage of the cycle. (More than one elementary body may be phagocytosed by a single host cell.)

Chlamydiae have a cell wall and two nucleic acids but are incapable of synthesizing ATP to meet their energy needs. Once the elementary body has been phagocytosed – it has an intrinsic property that allows it to circumvent host cell defenses that would normally lyse the phagosome – it becomes reorganized into the initial body. Larger than the elementary body, the initial body diverts the host cell's synthetic functions for its own metabolic purposes and proceeds to divide by binary fission, producing daughter microcolonies of chlamydiae. About 18 to 24 hours after infection, the initial bodies become reorganized into elementary bodies that subsequently exit the now disrupted host cell, ready to infect new host cells. The full cycle takes about 40 hours. The sequence results in a slow, steady accumulation of chlamydial particles within infected cells – the intracellular inclusions that are the diagnostic hallmark of chlamydial infection.

Several features distinguish the two species of chlamydiae. The inclusions of *C. trachomatis* accumulate glycogen and thus stain with iodine, whereas the inclusions of *C. psittaci* do not. Another difference is their response to sulfonamides – *C. trachomatis* is sensitive, *C. psittaci* is not. In addition, *C. trachomatis* is primarily a human pathogen, while *C. psittaci* causes disease in humans only via zoonoses, such as psittacosis and ornithosis.

The *C. trachomatis* species can be further subdivided into strains causing lymphogranuloma venereum (three serotypes) and strains causing ocular-genital infections (12 serotypes). The two subgroups differ significantly in their biologic activity. The lymphogranuloma venereum strains are more invasive, being capable of spontaneous cell-to-cell serial transmission in tissue culture and in vivo invasion of many tissues in addition to epithelial cells. The ocu-

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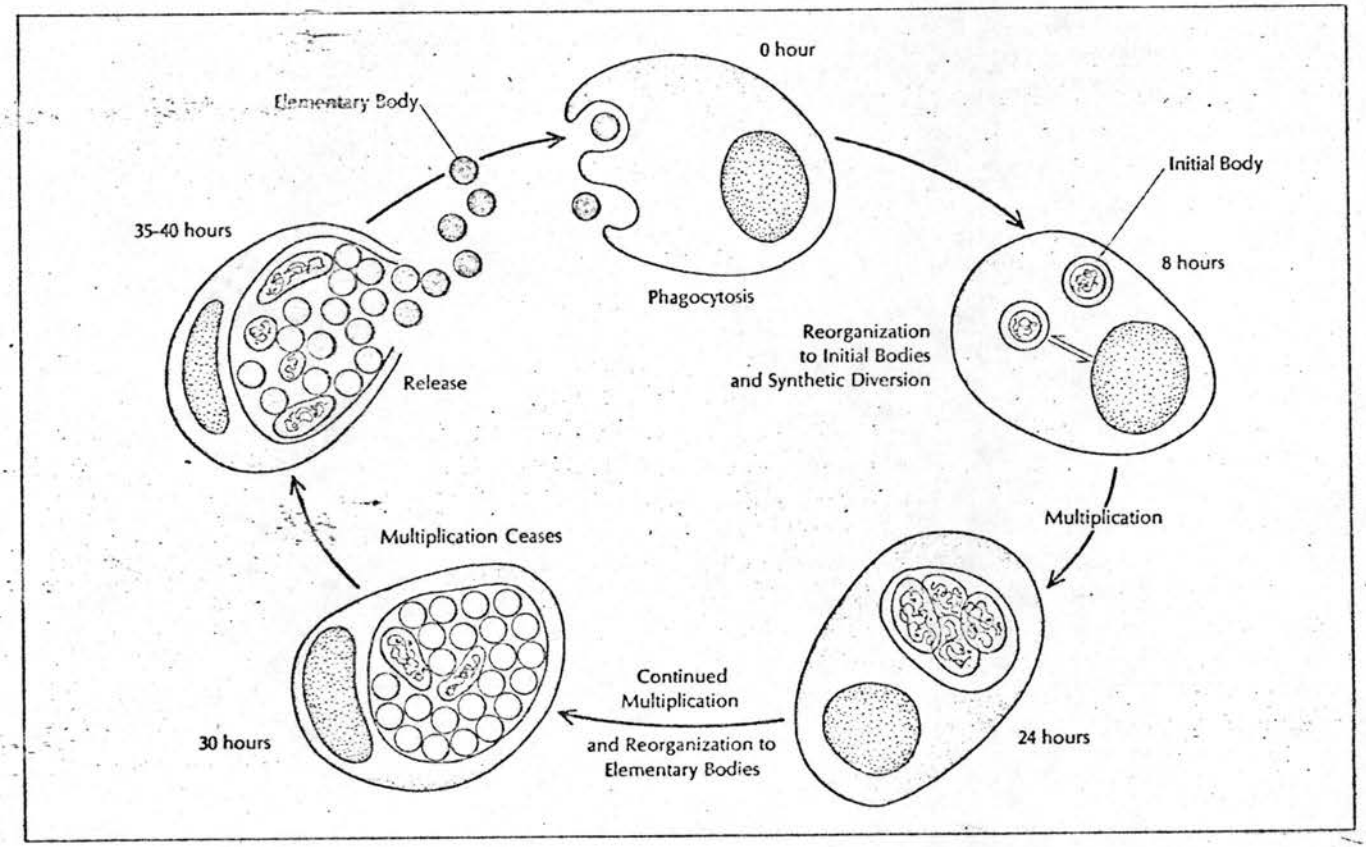
lar-genital strains are not readily invasive in tissue culture and apparently grow in vivo only in columnar epithelial cells, which are found in the conjunctiva, respiratory tract, gastrointestinal tract, cervix, urethra, and rectal mucosa.

The relationship between inclusion conjunctivitis in the infant and genital tract infection in the mother has been recognized since the beginning of this century, after a precedent was established with recognition of the cause-effect relationship between maternal gonorrhea and ophthalmia neonatorum. The characteristic inclusions of *C. trachomatis* were first described in conjunctival cells from patients with trachoma in 1907. Soon after, they were identified in conjunctival scrapings from infants with nongonococcal ophthalmia neonatorum and adults with conjunctivitis and in cells from the genital tracts of adults with urethritis or cervicitis. The relationship between parental genital infection and infant ocular infection was demonstrated cytologically before 1910. By 1911, the German ophthalmologist K. Lindner had enough evidence to suggest that almost 30% of nongonococcal urethritis was caused by the same agent that caused both infant and adult inclusion conjunctivitis. The organism, now known as *C. trachomatis*, was finally isolated in 1957 by F-F T'ang in mainland China, using embryonated hens' eggs. The use of penicillin and streptomycin was the usual method of preventing bacterial contamination in cell cultures at that time. Penicillin was not then being manufactured in China and was scarce. Perhaps this was fortunate since it turned out that *C. trachomatis* is sensitive to penicillin, and the required trick was to grow it in a medium containing streptomycin alone. Subsequently, during the 1960s, a number of investigators retraced the pattern of infection by isolating the organism from the conjunctivas of infants with inclusion conjunctivitis, from the genital tracts of men with urethritis and of women with cervicitis, and from both the eyes and genital tracts of adults with inclusion conjunctivitis.

In several prospective studies, the prevalence of chlamydial infection in pregnant women has been found to vary from 2% in Boston to 6% in San Francisco to between 8% and 13% in Seattle. The differences between population groups are probably not geographic but relate to demographic differences in the study groups, which, in turn, relate to past experience with chlamydial infection. Women with chlamydial genital tract infection generally tend to be young, to come from low socioeconomic groups, and to have a history of venereal disease.

Two years ago, we undertook a pilot study at University Hospital, Seattle,




*Life cycle of chlamydial organisms begins when small elementary bodies infect host cell by inducing active phagocytosis. During the next eight hours they reorganize into the larger reticulated initial bodies, which then divert the cell's synthetic functions to their own metabolic needs and begin to multiply by binary fission. About 24 hours after infection, the daughter organisms begin reorganizing into infective elementary bodies. At about 30 hours, multiplication ceases, and by 35 to 40 hours, the disrupted host cell dies, releasing new elementary bodies that can infect other host cells and thus continue the cycle.*

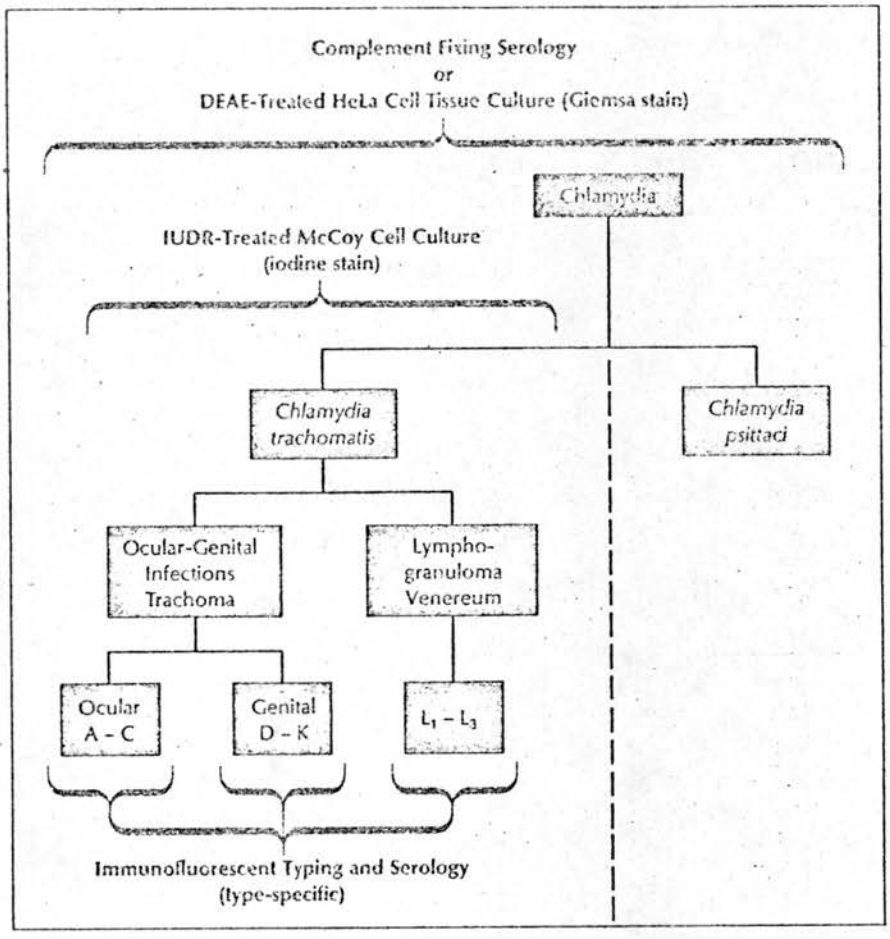
to assess the risk of neonatal infection and disease in infants born to mothers with chlamydial genital infection. In the study, 142 unselected pregnant women attending a prenatal clinic at the hospital had cervical cultures done for evidence of chlamydial infection. The cultures of 18 women were positive at 36 to 40 weeks gestation, and eight of the 18 infants born to these women developed conjunctivitis. Follow-up studies at one year of age revealed that 12 of the same 18 infants had serum antibody to genital strains of *C. trachomatis*, including six who had had no history of neonatal conjunctivitis.

These findings indicated an infection rate of 13% in the obstetric clinic population and of 6% in the total group of infants. Both figures are considerably higher than any previously reported. A study at University Hospital 10 years ago found chlamydial infection in 1.3% of pregnant women attending the obstetric clinics. Other investigators have reported inclusion conjunctivitis in fewer than 1% of infants. The higher incidence detected in our study may reflect an increase in prevalence of the organism or in detection of less severe conjunctivitis, or both. In any case, the results not only confirm that inapparent infection of neonates occurs but that it may be relatively common. Recently, the results of another pilot study by Julius Schachter and associates at the University of California, San Francisco, showed that 10 of 25 infants born to mothers with chlamydial genital tract infection had laboratory-proved inclusion conjunctivitis. Thus, it appears that the risk of eye infection is between 33% and 50%. In other words, one third to one half of the babies born to infected women will develop inclusion conjunctivitis, while, on the basis of the Seattle findings, approximately two thirds will give evidence of having been infected. Installation of silver nitrate in the eyes of newborns as prophylaxis for ophthalmia neonatorum apparently does not affect *C. trachomatis*, since all of the infants in our study received it.

Inclusion conjunctivitis of the newborn usually develops between seven and 14 days following delivery. It should be differentiated from chemical conjunctivitis due to silver nitrate, which usually appears within the first four days, and from gonococcal ophthalmia neonatorum, which characteristically becomes severe in the first week of life.

Inclusion conjunctivitis produces congestion and edema and some discharge, which may become serosanguineous if the conjunctiva is acutely inflamed. Follicles are not seen on the conjunctiva of the infant as they are in trachoma and adult inclusion conjunctivitis. The infant conjunctiva apparently is not capable of producing a follicular reaction to any stimulus.

The diagnosis can be confirmed readily in most cases by taking a scraping of the upper or lower conjunctiva and staining with Giemsa stain, which reveals the characteristic inclusions. The definitive diagnosis is made by culturing the organism. T'ang's time-consuming egg-yolk culture method has been supplanted by cell culture. The cells most often used are McCoy cells, which are first treated by irradiation or by treatment with 5-iodo-2-deoxyuridine (IUDR), cycloheximide, or cytochalasin B. The effect of this treatment is not fully known but it appears to affect cell growth. Some laboratories use L cells or HeLa cells. Prior to incubation, the inoculum is centrifuged with the cell substrate to obtain cell infection. Hospital laboratories are not usually equipped for this procedure, although many large medical center laboratories are developing the capacity to culture the organism.




*Flow chart summarizes current knowledge of Chlamydia taxonomy and the various laboratory procedures used in identifying and differentiating the organisms. All Chlamydia can be demonstrated by complement fixation or by HeLa cell-tissue culture methods. To differentiate between* C. trachomatis, *a primary human pathogen, and* C. psittaci, *largely an animal pathogen, the IUDR-treated McCoy cell culture method is used. For differentiation among strains causing ocular, genital, and lymphogranuloma venereum infections, immunofluorescent and serologic typing is necessary.*

**Clinical and Laboratory Data for Infants Born to Mothers with Genital Chlamydial Infection**

| Patient Number | Conjunctivitis (age in weeks at onset)* | Culture for Chlamydia | Typical Inclusions on Giemsa Stain | Fluorescent Antibody (FA) for Chlamydia Antigens on Smear | Tear Antibody (age in weeks at first positive test) | Serum Antibody at 1 Year of Age | Clinical Findings** at 1 Year of Age |
|---|---|---|---|---|---|---|---|
| 1 | ◐ | ◐ | | | ◐ (30) | ◐ | ○ |
| 2 | ◐ | ◐ | | | ◐ | ◐ | ○ |
| 3 | ◐ | ◐ | | | ◐ | ◐ | |
| 4 | ◐ | ◐ | | | ◐ | ◐ | ○ |
| 5 | ◐ | ◐ | | | ◐ | ◐ | ○ |
| 6 | ◐ | ◐ | | | ◐ | ◐ | ○ |
| 7 | ◐ | ◐ | | | ◐ (12) | ◐ | ○ |
| 8 | ◐ | ◐ | ◐ | ◐ | ◐ | ◐ | ○ |
| 9 | ◐ | ◐ | | | ◐ | ◐ | ○ |
| 10 | ◐ | ◐ | | | ◐ (20) | ◐ | ◐ |
| 11 | ◐ (1) | ◐ | ◐ | ◐ | ◐ (10) | ◐ | ○ |
| 12 | ◐ (5) | ◐ | ◐ | ◐ | ◐ (14) | ◐ | ○ |
| 13 | ◐ (6) | ◐ | ◐ | ◐ | ◐ (12) | ◐ | ○ |
| 14 | ◐ (6) | ◐ | | | ◐ | ◐ | ◐ |
| 15 | ◐ (1) | ◐ | | | ◐ | ◐ | ○ |
| 16 | ◐ (1) | ◐ | ◐ | ◐ | ◐ | ◐ | ○ |
| 17 | ◐ (2) | ◐ | ◐ | ◐ | ◐ | ◐ | ◐ |
| | ◐ (8)† | ◐ | ◐ | ◐ | | | |
| 18 | ◐ (2) | ◐ | ◐ | ◐ | ◐ (12) | ◐ | ◐ |
| | ◐ (8)† | ◐ | ◐ | ◐ | | | |

◐ Negative ◐ Positive *Conjunctivitis: ◐ Mild ◐ Severe †Recurrence
**Clinical Findings: ○ Normal ○ Micropannus

Serologic identification of the organism is also possible, but that will probably remain a function of research laboratories until a radioimmunoassay or a similar method is developed.

Inclusion conjunctivitis of the newborn, if untreated, usually lasts for one to two weeks, and whether or not it is treated, recurrence once or twice over the next two to three months is common. The treatment usually recommended is topical sulfacetamide, but orally administered erythromycin may be preferable. Controlled trials of erythromycin have not been completed, but use of the antibiotic appears to result in fewer relapses.

In general, inclusion conjunctivitis of the newborn is a benign, self-limited disease, but there is some evidence that this is not always the case. C.H. Mordhorst in Denmark has found, from long-term follow-up of families with chlamydial ocular-genital infections, that scarring, pannus formation and other characteristics usually associated with trachoma do occur in some patients, presumably as a result of reexposure.

The difference between trachoma in the Middle East, Asia, or Africa, where it is hyperendemic, and the entity of inclusion conjunctivitis in the United States and other developed nations is difficult to define other than on the basis of severity and sequelae. Clearly the two diseases are different in these two respects. The monkey model developed by S-P Wang and J.T. Grayston at the University of Washington has provided some explanation of these differences. When monkeys are inoculated on the conjunctiva with any of the ocular-genital *C. trachomatis* organisms, an acute follicular conjunctivitis develops that has the characteristics of trachoma. The disease is the same whether the organism was isolated from a case of inclusion conjunctivitis or nongonococcal urethritis in Seattle or from a case of trachoma in Egypt. In fact, if any difference is worth noting, it is that isolates from genital sources produce more severe disease in the monkey than isolates from trachoma.

In the monkey model, initial infection is self-limited. Pannus, which involves neovascularization across the limbus of the cornea and is a diagnostic sign of trachoma, develops in the monkey only after reinfection or on initial infection of a monkey previously sensitized by killed antigen. In other words, pannus formation denotes prior sensitization with the antigen. Other characteristics of trachoma that eventually lead to blindness, such as conjunctival scarring and deformation, entropion, and trichiasis, also develop in the monkey model after reinfection. It is highly probable that in countries where trachoma is not endemic, such as the United States, inclusion conjunctivitis represents a pri-

mary chlamydial infection. Although rare, more severe ocular infections that are clinically indistinguishable from trachoma occur in this country; on the basis of present evidence they probably represent reinfection. One other factor that affects severity is the presence of other bacterial eye infections. In fact, the distinguishing feature between trachoma-hyperendemic countries with or without blindness is the presence or absence of bacterial conjunctivitis in these respective populations.

Within the last two years, another risk to the newborn of maternal chlamydial infection has been documented. In 1977, Marc O. Beem and associates at the University of Chicago described a distinct pneumonia syndrome in infants who had previously had inclusion conjunctivitis. They showed that the pneumonia was related to *C. trachomatis* infection by isolating the organism from the nasopharynx and tracheal secretions of infants with the syndrome and by demonstrating that the infants developed specific antibody to *C. trachomatis*.

Several features distinguish pneumonia due to *C. trachomatis*. It develops between about four and 18 weeks of age and produces an afebrile illness with symptoms of congestion, wheezing, and a distinctive staccato cough. The paroxysms of staccato cough are not unlike those of pertussis, but they lack the inspiratory whoop that characterizes that disease. The clinical findings include diffuse crepitant rales on auscultation of the chest; hyperinflation of the lungs is seen on x-ray. Other characteristics of *C. trachomatis* pneumonia are an increase in eosinophils in peripheral blood (greater than 400 eosinophils per cubic mm) and elevated serum immunoglobins. We find that an IgG $\geq$500 mg/100 ml or an IgM $\geq$110 is characteristic of *C. trachomatis* pneumonia.

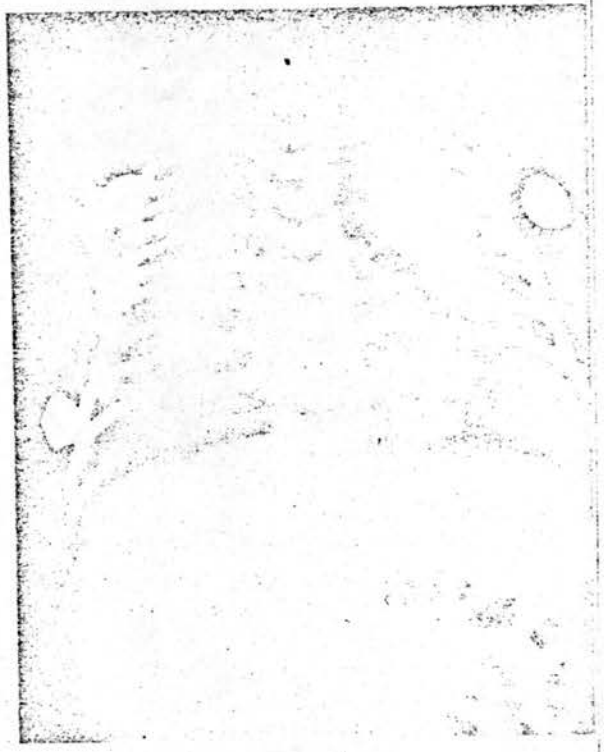
The diagnostic tests used for *C. trachomatis* pneumonia include recovery of the organism from the nasopharynx or tracheal secretions and various serologic techniques. The organism is quite distinctly localized to the posterior nasopharynx, and it is infrequently recovered from the oropharynx. Thus, the most appropriate methods for recovery are either a posterior nasopharyngeal swab or aspiration of nasopharyngeal secretions with a feeding tube attached to a syringe. Antibodies against *C. trachomatis* can be demonstrated in the serum. Local antibody can be demonstrated either in the nasopharyngeal secretions or in the tears, but this information adds little to the significance of the serum antibody test results.

The evidence that *C. trachomatis* is the causative agent of the pneumonia syndrome is based on recovery of the agent from nasopharyngeal and tracheal secretions of infants with typical symptoms and, in three instances, from lung biopsy material. On the other hand, *C. trachomatis* has rarely been isolated from lung biopsy material, and inclusions have rarely been seen in such material. Consequently, some investigators have suggested that the syndrome is due to hypersensitivity rather than infection, and others have suggested that viruses, which are quite often found in association with *C. trachomatis*, are involved in the infection that produces the pneumonia.

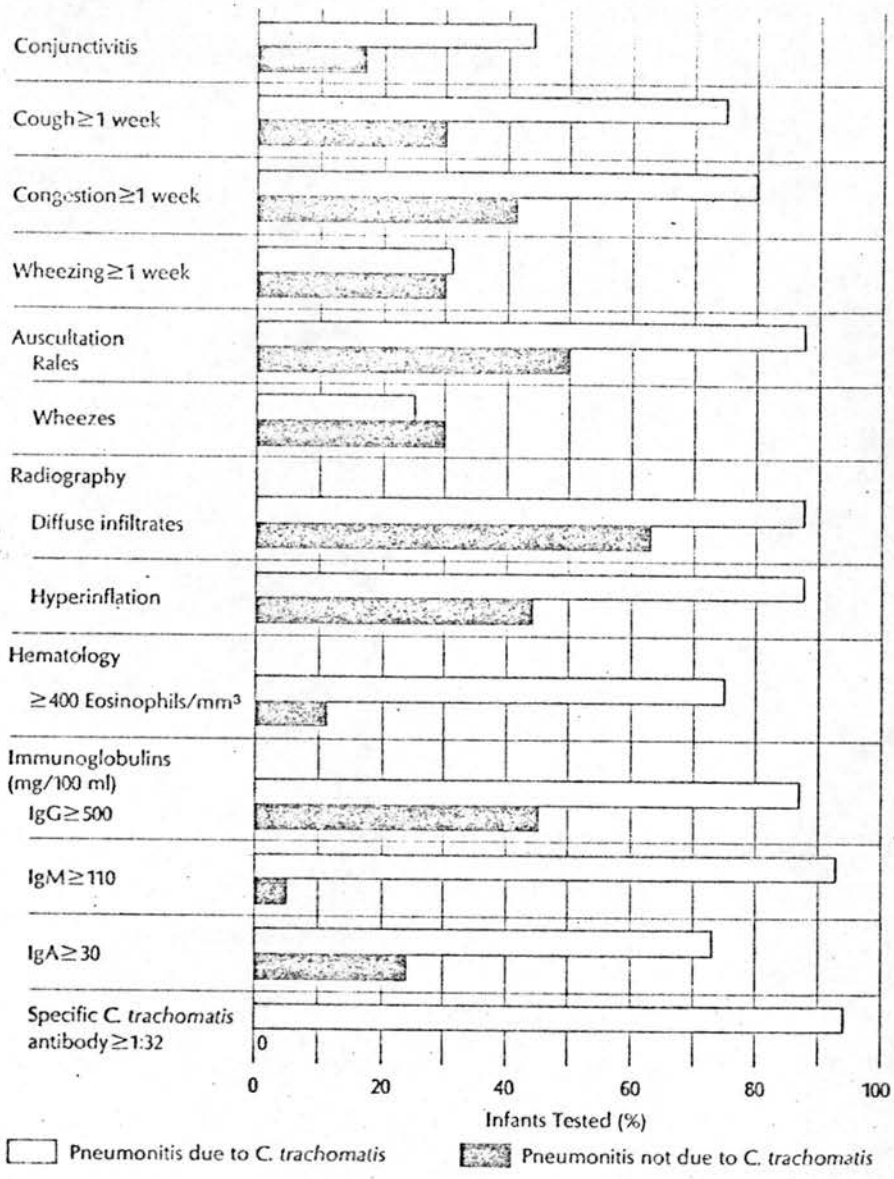
The viruses associated with *C. trachomatis* in infants with pneumonia include cytomegalovirus, respiratory syncytial virus, rhinovirus, adenovirus, and enterovirus. However, available evidence indicates that *C. trachomatis* is the central etiologic agent in the disease. Beem and associates have noted that symptoms and clinical and laboratory findings are the same in infants from whom *C. trachomatis* alone is isolated and in those from whom both *C. trachomatis* and viruses are isolated. Furthermore, they found that the clinical course and the response to treatment were similar, regardless of whether *C. trachomatis* was isolated alone or in combination with viruses. In addition, our experimental results support the view that the pneumonia is due to *C. trachomatis*. We were able to induce the pneumonitis in infant baboons by inoculation with *C. trachomatis* and then recovered the organism from the lungs. Since *C. trachomatis* pneumonia is a chronic illness, which in many cases produces only mild to moderate symptoms, and respiratory viral infections are common in infants, it would not be too surprising to find frequent coinfection with these agents. The relationship between *C. trachomatis* pneumonitis and cytomegalovirus infection remains to be explored, but it should be noted that both are venereally transmitted agents that appear together in other epidemiologic settings. It should also be noted that the *C. trachomatis* serotypes recovered from infants with pneumonitis are the same as those recovered from genital sources.

Examination of lung biopsy material has revealed slight but intense infiltration of mononuclear cells in small airways, often causing blockage that presumably results in the hyperinflation typical of the disease. Although there is some observable damage to bronchial and pulmonary epithelium, it is not marked.

Controlled clinical trials of treatment of *C. trachomatis* pneumonia have been started only recently, therefore the preferable therapy remains to be demonstrated. In vitro tests with a variety of antibiotics have shown that tetracyclines and erythromycin are the most effective agents against the organism. Since tetracyclines should not be used in infants and children be-



*Hyperinflation of the lungs is a consistent finding in chest x-rays of infants with proven chlamydial pneumonitis.*




*Clinical and laboratory findings in infants with afebrile pneumonitis (16 with proven chlamydial infection, 27 without evidence of chlamydial infection) are graphed. Findings characteristic of chlamydial pneumonitis were a staccato cough, lung hyperinflation and increased eosinophils and serum immunoglobulins.*

cause of their effect on growing teeth, erythromycin is probably the drug of choice. Sulfisoxazole is somewhat less effective but can be used. Prolonged follow-up seems advisable in view of the well-known tendency of chlamydial infections to recur, even in treated patients. In this regard, our preliminary observations of the antibody response in treated infants are of interest. Administration of systemic antibiotics, even relatively ineffective ones, such as penicillin, had a depressing effect on antibody titers when compared with infants not given systemic antibiotics, or given topical ocular antibiotics only. Whether or not early systemic antibiotic treatment affects the immune response is not known. Beem found that systemic treatment with either sulfisoxazole or erythromycin produced clinical improvement of respiratory symptoms within one week and rapidly terminated shedding of *C. trachomatis*.

The risk of *C. trachomatis* pneumonia in babies born to infected mothers has not been determined. The early results of a number of prospective studies suggest that it is at least 5% and perhaps as high as 25%.

At the present time the only clinical entities definitely associated with natally acquired chlamydial infection are inclusion conjunctivitis and pneumonia, but it is reasonable to expect that a relationship with other diseases will be found. For instance, Beem and associates found middle-ear abnormalities in more than half of 41 infants with *C. trachomatis*-positive pneumonia. The abnormalities consisted of an opaque, pearly-white color, diffuse-light reflex, poorly distinguishable short process, and, in some cases, bulging of the tympanic membrane. Myringotomies done on one or both ears of 11 of these infants consistently yielded gelatinous middle-ear secretions, and *C. trachomatis* was isolated from ear aspirates of three infants. The finding suggests that *C. trachomatis* may contribute to otitis media in infancy. Such a possibility and its potential long-term effects need to be evaluated.

Similarly, it is unlikely that pneumonia is the only respiratory consequence of nasopharyngeal infection with *C. trachomatis* in infancy. Our experience, as well as that of other investigators, suggests that by one year of age, children who have had *C. trachomatis* infections in infancy have an excess in both frequency and severity of respiratory infections. The extent and characteristics of both upper and lower respiratory tract infections without pneumonia have not been defined.

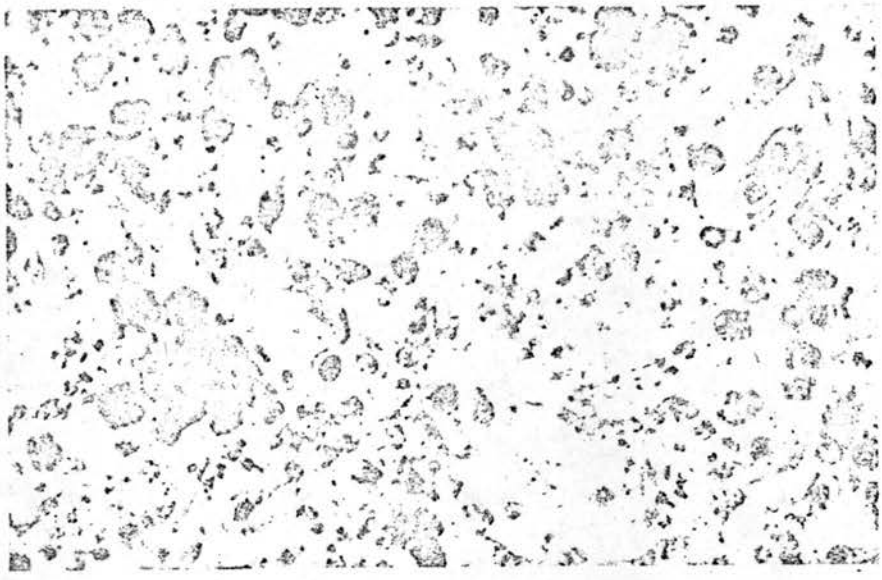
It is also likely that *C. trachomatis* will be found to contribute to respiratory infections at older ages. The results of serologic studies done by Grayston and Wang indicate that *C. trachomatis* infection in infancy has a continuing effect on respiratory infections at older ages.

Our finding that 13 of 14 infants with *C. trachomatis* pneumonitis had positive tear antibody tests suggests a high incidence of inapparent and apparent conjunctivitis prior to the development of pneumonitis. Half of these infants had histories of conjunctivitis, which suggests that nasopharyngitis and pneumonitis may occur by direct extension down the respiratory tract from an ocular focus. It is also likely that a heavy intrapartum

dose of *C. trachomatis* could infect both conjunctiva and nasopharynx concurrently, and even the lower respiratory tract by aspiration.

The possibility of preventing inclusion conjunctivitis of the newborn is currently under investigation. The basis for the present approach is the success of mandatory silver nitrate prophylaxis in preventing ophthalmia neonatorum. Several studies are in progress to test the effectiveness of erythromycin ointment as a substitute for silver nitrate in the prevention of both gonococcal and chlamydial infections of the eyes in newborns. If the results are definitive, erythromycin may become the recommended agent for neonatal ocular prophylaxis in the future. However, it is unlikely that topical ocular erythromycin will prevent nasopharyngeal infection of the newborn or its apparent sequela, respiratory disease.

The most effective preventive of natally acquired chlamydial infections would be detection and treatment of pregnant women prior to delivery. Unfortunately, no simple, routinely applicable method is available for such a course of action. Diagnostic tests for identifying *C. trachomatis* genital infections are not universally available. While the typical chlamydial inclusions are readily apparent in conjunctival smears, they are infrequently found in cervical smears. For diagnosis of both male and female genital infection, the organism must be recovered on a swab and then isolated in tissue culture. Furthermore, chlamydial infection in women is not usually accompanied by any manifest disease of the cervix, although one clinical entity, a hypertrophic papillary cervicitis, has been described in association with *C. trachomatis* genital infections in women. Another problem arises from the observation that some women who are found to be *C. trachomatis*-positive early in preganancy spontaneously revert to negative before delivery. And, vice versa, some women who are negative on first examination become positive later in pregnancy. These cases may represent a flare-up of latent cervical infection related to the immunologic changes that occur in pregnancy. In fact, the majority of women with proven chlamydial cervical infection during pregnancy spontaneously revert to negative postpartum. In addition, when the sexual partners of pregnant women with chlamydial cervical infection have been studied, the great majority have been found to have chlamydial urethral infection. Although most of these cases have been asymptomatic, there is usually a history of past urethritis.



*Iodine stain reveals typical chlamydial inclusion bodies in McCoy cell culture. To obtain growth of the organism, cells were pretreated with 5-iodo-2-deoxyuridine.*

Until we have a better understanding of the natural history of *C. trachomatis* infections in pregnancy, it would seem more important to identify women as infected or not in the last trimester in order to define those at risk of infecting their infants.

Regardless of whether the diagnosis is made in early or late pregnancy, another problem arises, and that is what antibiotic to use in treatment of the mother. Again, although there are no recommendations in this area at the present time in the United States, the common practice in the United Kingdom is to treat infected pregnant women with erythromycin. Sexual partners should be treated at the same time to prevent maternal reinfection. (The diagnosis and treatment of genital chlamydial infections will be discussed in more detail in a subsequent article.) □

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# *Chlamydial infection of mothers and their infants*

*In 340 women, cultured prospectively during their pregnancies, the rate of infection with* Chlamydia trachomatis *was 8.8%. The women with positive cultures tended to be younger and more often single and black than their counterparts with negative cultures. There were no statistically significant clinical differences between the two groups. Eighteen children born to* Chlamydia *culture-positive women and 16 born to negative women were followed for nine months to examine the potential effects of maternal infection on infant growth, development, and illness. Eleven of 18 study patients had culture or tear antibody evidence of* Chlamydia *infection, as opposed to one of the control subjects (P = 0.00093). Eight of these 11 had clinical conjunctivitis, and two of the eight developed pneumonia. Growth retardation and developmental abnormalities were not detected in either group. It is concluded that maternal carriage of* C. trachomatis *is associated with a high incidence of clinical illness in the offspring.*

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**San-pin Wang, M.D., and Kenneth McIntosh, M.D., with the technical assistance of Cynthia Wintersgill, B.A., Jane Allaman, B.S., and Inara Orr, R.N.,** *Denver, Colo., Atlanta, Ga., and Seattle, Wash.*

CHLAMYDIAL INFECTIONS are regularly associated with certain nonspecific genital syndromes in both men and women.[1] These syndromes may well be the most common sexually transmitted diseases in the United States (Center for Disease Control, Venereal Disease Control Division, Atlanta, Georgia: unpublished data), but clinical manifestations are usually not severe, and long-term sequelae are not well documented. The recent description of a protracted pneumonia associated with *Chlamydia trachomatis* in infants[2-5] has shed new light on the importance and potential public health impact of genital carriage of *Chlamydia.* There is at present little information concerning the risk associated with chlamydial infection in pregnant women and their offspring.[6] In this study we cultured a large group of mothers prospectively during their pregnancies. Infants born to *Chlamydia* culture-positive and *Chlamydia* culture-negative women were followed to trace the development of disease and disability.

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**Reprint address: Technical Information Service, Center for Disease Control, Atlanta, GA 30333.*

## MATERIALS AND METHODS

**Maternal population.** Between October 3, 1975, and March 5, 1977, 340 women attending the Obstetrics Clinic of the Colorado General Hospital, at low risk for the complications of pregnancy and at less than 32 weeks' gestation on first visit, were enrolled in the study. Participation was voluntary and written informed consent was obtained.

Demographic data and information relating to current sexual activity were obtained from each patient. A cervical culture for *Chlamydia* was taken at the initial obstetric evaluation, at 32 weeks' gestation, at parturition, and at the postpartum visit. More frequent cultures were usually obtained from women found to be *Chlamydia* culture positive. Serum was also obtained at each visit and frozen at −20°C. In addition, cervical and urine cultures for *Herpesvirus hominis* and cytomegalovirus were obtained at each visit. All women underwent cervical culture for *Neisseria gonorrhoeae* on the first two visits; appropriate treatment and epidemiologic follow-up were offered to all

Table. Clinical and laboratory results in *Chlamydia* culture-positive study group

| *Mothers* | | | *Infants* | | | | | |
|---|---|---|---|---|---|---|---|---|
| *Evidence of* C. trachomatis *infection* | | | *Evidence of* C. trachomatis *infection* | | | | | |
| *Patient No.* | *By culture of cervix (wk gestation)* | *By serum antibody (type)* | *By culture* | | *By tear antibody* | | *Conjunctivitis* | *Comments* |
| | | | *Site‡* | *Age (wk)* | *Type* | *Age (wk)* | | |
| 1 | 16 | ED | – | – | Neg | | No | |
| 2 | 31 | F† | – | – | GF | 5, 17, 24, 46 | No | Bilateral micropannus at 1 yr |
| 3 | 13 | GF | – | – | Neg | | No | |
| 4 | 32, 38, 39* | GF | – | – | GF | 39 | No | |
| 5 | 35 | ED | R | 5 | ED | 24, 43 | Yes | Mother positive 6 wk postpartum |
| 6 | 22, 28 | ED | NP | 7 | ED | Birth, 7, 26 | Yes | Infant developed pneumonia at 4 wk of age |
| 7 | 24, 33, 35, 37 | Ed | – | – | Neg | | No | Infant developed recurrent wheezing at 6 wk |
| 8 | 32, 36, 38* | GF | NP | 11, 27 | GF | 13, 27 | Yes | Infant developed pneumonia at 6 wk of age; mother positive 6 wk postpartum |
| 9 | 32 | H | – | – | Neg | | No | |
| 10 | 22, 31, 40* | ED | NP | 13 | ED | 13 | No | Bilateral micropannus at 1 yr |
| 11 | 30, 35 | GF | – | – | Neg | | No | |
| 12 | 23 | I | – | – | Neg | | No | |
| 13 | 19 | ED | – | – | Neg | | No | |
| 14 | 34 | ED | – | – | ED | 18 | Yes | |
| 15 | 32, 37 | D† | NP | 2 | ED | 9, 13 | Yes | Bilateral micropannus and small anterior stromal opacity, o.s. at 1 yr |
| 16 | 35 | ED | R | 3 | ED | 9, 17, 26, 46 | Yes | Mother positive 6 wk postpartum |
| 17 | 17, 24 | ED | C<br>NP | 3, 5, 17<br>17 | ED | 17, 33, 40 | Yes | |
| 18 | 22, 30, 36, 41* | ED | NP, R | 12 | ED | 12 | Yes | |

*Day of delivery.
†Isolate was typed and confirmed the antibody type in serum.
‡R = Rectal, NP = nasopharynx, C = conjunctiva, – = not done.

women with positive cultures. A total of 775 chlamydial cultures were obtained during pregnancy or at delivery from the 340 women.

**Infant population.** Infants born to 18 of the 30 Chlamydia culture-positive women were followed from birth to 9 months of age, along with a control population of infants born to mothers who remained *Chlamydia* culture-negative throughout pregnancy; 12 of the culture-positive women either were lost to follow-up or refused further participation. Control infants were, as often as possible, those born at the next delivery of a *Chlamydia* culture-negative mother following each Chlamydia culture-positive delivery; when this was not possible, the infant born at the closest subsequent delivery of a negative mother was then accepted. Eighteen mothers and their 19 infants (including one set of twins) were originally enrolled in the control group. Eight of these 18 mothers had serum antibody detected in an initial screening test, indicative of previous *Chlamydia* infection. All eight were further examined for IgM antibody; three had anti-*Chlamydia* IgM which was thought to be suggestive of recent (although not necessarily current) infection. They were omitted from the analysis. Careful cultural, serologic, and clinical follow-up of the infants of these three mothers revealed no evidence of chlamydial infection in any.

A separate informed written consent was signed by both parents for inclusion of the child in the study. All infants followed were delivered vaginally, and silver nitrate ophthalmic prophylaxis was employed in all instances. At birth and at two to three weeks of age, the conjunctiva, nasopharynx, umbilicus, genitals, and rectum were cultured for *Chlamydia*. At six weeks, three months, and nine months the conjunctiva, nasopharynx, genitals, and occasionally the rectum were cultured. Infants in the infected group were each cultured an average of 5.4 times, and those in the control group an average of 5.6 times.

Tear secretions for antibody determination were obtained at the time of follow-up cultures, starting usually at two to three weeks of age. Cord blood IgM determina-

tions were performed in most instances. Height, weight, and head circumference were determined routinely, as was psychomotor development through use of the Denver Prescreening Developmental Questionnaire.[7] Infants were examined and evaluated by one of us (G. T. F.) at each follow-up visit. All infants were observed for eye disease (conjunctivitis with exudate of any type) and pneumonia as well as other clinical illness. Children with evidence of chlamydial eye disease during the study period were re-examined at one year of age.

Compliance with the protocol was excellent among control patients and somewhat less good in the infected group, who, perhaps because of their sociodemographic characteristics (see below), tended to miss appointments and move without leaving forwarding addresses. Because of this difficulty, cultures were often not taken during acute illness, conjunctivitis in particular.

**Chlamydia cultures.** Infant nasopharyngeal specimens were obtained using a sterile 8-French suction catheter inserted through the nares to the posterior pharynx. Secretions were aspirated and placed in transport media. All other specimens were obtained using sterile cotton-tipped applicators. Specimens were frozen at −70°C until processed. Chlamydiae were isolated according to the method of Wentworth and Alexander,[8] using McCoy cells treated with IUdR.

**Tear antibodies and serologic studies.** Tear secretions were collected from the study and control infants by means of a 5 × 20 mm strip of filter paper applied along the lower lid margin of each eye with sterile forceps. After complete saturation, the filter paper strips were placed in vials containing 0.2 ml of phosphate-buffered saline, yielding an approximate tear dilution of 1:10. Serum antibody was measured in mothers in the study and control groups. Both tear and serum antibody were determined by the microimmunofluorescence method, using CJ, A, H, I, K, B, ED, and GF antigens and a conjugate containing antihuman IgM, IgA, and IgG combined (Hyland Laboratories, Los Angeles, Calif.). Titers of 1:8 for serum and 1:10 for tears (the lowest tested) were considered positive. Some positive sera were further analyzed using separate anti-IgM and IgG conjugates.[9] In two study mothers in whom the predominant antibody type in the serum was in doubt, the cervical isolates were examined in order to determine the precise infection serotype (Table). Cord blood IgM determinations were made by radial immunodiffusion (TRI-Partigen IgM Standard Kit, Behring Diagnostics).

**Other cultures.** *Herpesvirus hominis* and cytomegalovirus were recovered in human embryonic lung fibroblasts and identified by routine virologic procedures. *Neisseria gonorrhoeae* was isolated on Thayer-Martin medium and identified by routine bacteriologic methods.

**Statistical analysis.** The Fisher exact test and the critical ratio for difference of proportions were used for statistical analysis.[10]

## RESULTS

**Maternal population.** Cultures obtained during pregnancy from 30 of the 340 women (8.8%) enrolled in the study grew *Chlamydia*. *Chlamydia* culture-positive women differed significantly from those who were *Chlamydia* culture-negative with regard to certain sociodemographic characteristics. They tended to be younger (53% in the 15 to 19 year age range vs. 27%, $P \leq 0.01$) and more frequently black (27% vs 9%, $P \leq 0.01$), or unmarried (33% vs. 14%, $P < 0.01$). More of the *Chlamydia* culture-positive women lived at home with their parents, perhaps as a correlate of age. The father of the child was usually the current sex partner in both groups, but among married *Chlamydia* culture-positive women, the husband was less likely to be the father of the child. There was no difference between the two groups with regard to income or enrollment on welfare.

The positive and negative groups were similar in clinical characteristics. There were no significant differences in previous obstetric history, complications of labor and delivery, condition at initial evaluation of the newborn child (Apgar score, birth weight, and estimated gestational age), and postpartum complications. Previous infection with *Chlamydia* in the maternal population can be judged by the prevalence of anti-*Chlamydial* IgG in culture-negative mothers. Of 18 women examined, eight had IgG antibody to one of the serotypes tested.

Ten of the 340 women (2 *Chlamydia* culture-positive and 8 culture-negative) were culture positive for *Herpesvirus hominis* and three (all *Chlamydia* culture negative) carried cytomegalovirus. Six patients had gonorrhea (2 *Chlamydia* culture-positive and 4 culture-negative).

**Infant population.** Eighteen infants (7 male and 11 female), delivered vaginally to women harboring *C. trachomatis* during gestation, were enrolled for follow-up study. Sixteen infants (9 male and 7 female) born to *Chlamydia* culture-negative women served as control subjects. There were no significant differences between the two groups with regard to gestational age, birth weight, length, head circumference, growth patterns, and psychomotor development during the study period.

Eleven infants (61%) in the study group developed evidence of infection with *C. trachomatis*. Eight of the 11 were culture positive from at least one site and all 11 developed tear antibody to *Chlamydia*. In 6 of these 11,

early tear samples were available and antibody was shown to be absent before infection. Eight infants developed conjunctivitis, with onset at one to nine weeks of age. Seven of these eight were culture positive (two from the conjunctiva itself and the remainder from other sites), and the eighth had only tear antibody. Of the three clinically normal infants with tear antibody, one was culture positive as well. In all instances, the infant tear antibody type was the same at that in maternal serum. Breast-feeding was weakly but not significantly associated with development of clinical conjunctivitis. In the study group, six of nine breast-fed infants developed conjunctivitis as against two of nine bottle-fed infants ($0.01 > P > 0.05$ by the Fisher exact test).

In contrast, only a single infant of a control mother developed evidence of *Chlamydia* infection ($P = 0.00093$ by the Fisher exact test). This child's mother had IgG (but no IgM) antibody to the GF serotype group of *Chlamydia*, but was never culture positive during pregnancy. The infant had purulent conjunctivitis at two weeks of age which was not cultured but which responded to sulfonamide therapy. Cultures taken at birth and 10, 23, and 35 weeks of age were negative. At 5 months of age antibody to the GF serotypes was found in her tears.

Two of the infants in the study group with conjunctivitis subsequently developed a chronic pneumonitis (onset at ages 4 and 6 weeks). Both were afebrile and had a dry, nonproductive cough, interstitial infiltrates on chest roentgenogram, and positive nasopharyngeal cultures. Other bacterial and viral cultures obtained from these infants were negative. One child required hospitalization and was treated with ampicillin and kanamycin parenterally for three days. The other was treated with erythromycin as an outpatient. Both recovered completely in four to six weeks.

One further child in the study group, without evidence of chlamydial infection, developed recurrent wheezing at 6 weeks of age. He was admitted at 3 months of age, when both viral and chlamydial cultures were negative, and discharged with a diagnosis of "asthma."

As shown in the Table, the nasopharynx was the most common positive culture site (seven of the eight infants). Three infants had positive rectal cultures and, as noted, two had positive conjunctival cultures as well. No cultures taken during the nursery stay grew *Chlamydia*. Initial isolations occurred between 2 and 13 weeks of age, in five of eight infants before 9 weeks of age. Shedding of the organism continued as late as 27 weeks in one instance. Tear antibody tended to become positive later than cultures, in 9 of 11 infants at or after 9 weeks of age. In one instance antibody was present at birth. Cord IgM levels were measured in 16 of the 18 study patients and in 13 of the 16 control subjects; all were within normal limits.

All 11 infants with evidence of Chlamydia infection had follow-up ophthalmologic examinations at one year of age. No active eye disease was found, but three of the infants had a mild bilateral micropannus. Two of three had not had previous clinical conjunctivitis or positive cultures, but did have tear antibody as evidence of infection. The third had, in addition, a small anterior stromal opacity in the eye from which a previous positive culture had been obtained. In no instance were these changes thought to be a hindrance to vision.

## DISCUSSION

Recent reports suggest that *C. trachomatis* may be an important pediatric pathogen in a nontrachomatous area such as the United States. Schachter et al[2] first reported a child with conjunctivitis and pneumonitis. Subsequently, Beem and Saxon[3] reported 12 cases of pneumonia in infants characterized by dry hacking cough, chronic pulmonary infiltrates, and an afebrile course. All of these children had positive nasopharyngeal cultures. Frommell et al[4] strengthened the association by obtaining a lung biopsy positive for *C. trachomatis* from another such patient. Chandler et al[5] cultured 142 women during the last month of gestation, of whom 18 were *Chlamydia* positive (12.7%). Eight infants born to these 18 women developed clinical conjunctivitis, although none developed pneumonia. Finally, a recent survey by Harrison et al[1] found chlamydial infection in 9 of 30 consecutive infants under 6 months of age hospitalized with pneumonia, and in only one of 28 matched control subjects. The clinical aspects of this characteristic subacute pulmonary disease were confirmed.

Our study is in agreement with these results and demonstrates the high rate of *Chlamydia* infection (61%) and clinical disease (44%) in infants born to *Chlamydia* culture-positive mothers. These results are of particular interest since women initially at high risk for complications of pregnancy were excluded. The social and demographic differences between *Chlamydia* culture-positive and culture-negative mothers are in agreement with those of Chandler et al[6] and may reflect increased sexual activity at an earlier age. There is no apparent association, however, between culture positivity and the clinical course of pregnancy and delivery. Similarly, maternal carriage of *Chlamydia* does not appear to affect the growth and development of the child, but seems to play a significant role in the appearance of *Chlamydia*-associated illness.

Only two infants in our study were found to shed *Chlamydia* from the conjunctivia, despite the presence of conjunctivitis in eight. In some other studies, *Chlamydia* have been cultured with apparent ease from the conjunctivae[3, 11] whereas in Chandler's study,[6] which was similar to the present survey in being prospective, only three of eight infants with conjunctivitis and born to a culture-positive mother yielded *Chlamydia*. Our low isolation rate was probably due to at least two features of the study: timing of cultures in relation to disease was often poor, owing in part to problems with follow-up of the infected group; and cultures were frozen before tissue inoculation. On the other hand, studies in monkeys[12] suggest that tear antibody develops only when infection of that eye has occurred. Moreover, early tear samples in the majority of our infected infant population showed no antibody; for this reason, it is unlikely, except in the possible instance of the infant positive at birth, that we were measuring maternal, passively acquired tear IgG. The data in our study are thus consistent with an etiologic relationship between conjunctivitis and *Chlamydia* infection.

The absence of elevated IgM in cord blood suggests that intrauterine infection did not take place. In most infants, the timing of the appearance of culture positivity and tear antibody is consistent with infection during passage through the birth canal. On the other hand, the association with breast-feeding (suggesting more intimate handling of the child by the mother) raises the possibility of postpartum transmission. In either event, *Chlamydial* carriage by the mother would appear to be associated with a high incidence of clinical illness in the child.

We are indebted to Dr. Watson Bowes, and the staff of the Obstetrics Clinic, Colorado General Hospital, for their support, and to Dr. S. Lance Forstat, for performing the ophthalmologic examinations.

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# GONORRHEA

## Center for Disease Control Recommended Treatment Schedules* 1979

*These recommendations were established after deliberation with these therapy consultants: HC Neu, MD, College of Physicians and Surgeons, Columbia University; EH Braff, MD, San Francisco Dept of Public Health; G Cunningham, MD, Southwestern Medical School, Dallas; KK Holmes, MD, PhD, USPHS Hospital, Seattle; F Judson, MD, Dept of Health and Hospitals, Denver; W McCormack, MD, State Laboratory Institute, Boston; EM Mears, Jr, MD, New England Medical Center, Boston; JD Nelson, MD, Southwestern Medical School, Dallas; M Nelson, MD, Orange County, Calif.; SM Sgroi, MD, Suffield, Conn.; F Sparling, MD, School of Medicine, The University of North Carolina, Chapel Hill; Lt. Col. EC Tramont, Walter Reed Army Medical Center, Washington, D.C.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES / PUBLIC HEALTH SERVICE / CENTER FOR DISEASE CONTROL

# GONORRHEA • CDC Recommended Treatment

## Uncomplicated Gonococcal Infections in Men and Women

### DRUG REGIMENS OF CHOICE

**Aqueous procaine penicillin G (APPG):** 4.8 million units injected intramuscularly at 2 sites, with 1.0 g of probenecid by mouth; **OR**

**Tetracycline hydrochloride†:** 0.5 g by mouth 4 times a day for 5 days (total dosage 10.0 g). Other tetracyclines are not more effective than tetracycline hydrochloride. All tetracyclines are ineffective as a single-dose therapy; **OR**

**Ampicillin or amoxicillin:** Ampicillin, 3.5 g, or amoxicillin, 3.0 g, either with 1 g probenecid by mouth. Evidence shows that these regimens are slightly less effective than the other recommended regimens.

Patients who are allergic to the penicillins or probenecid should be treated with oral tetracycline as above. Patients who cannot tolerate tetracycline may be treated with spectinomycin hydrochloride, 2.0 g, in 1 intramuscular injection.

### SPECIAL CONSIDERATIONS

Single-dose treatment is preferred in patients who are unlikely to complete the multiple-dose tetracycline regimen. The APPG regimen is preferred in men with anorectal infection.

Pharyngeal infection is difficult to treat. High failure rates have been reported with ampicillin and spectinomycin.

Tetracycline treatment results in fewer cases of postgonococcal urethritis in men. It may eliminate coexisting chlamydial infections in men and women.

Patients with incubating syphilis (seronegative, without clinical signs of syphilis) are likely to be cured by all the above regimens except spectinomycin. All patients should have a serologic test for syphilis at the time of diagnosis.

Patients with gonorrhea who also have syphilis or are established contacts of syphilis patients should be given additional treatment appropriate to the stage of syphilis.

### TREATMENT OF SEXUAL PARTNERS

Men and women exposed to gonorrhea should be examined, cultured, and treated at once with one of the regimens above.

### FOLLOW-UP

Follow-up cultures should be obtained from the infected site(s) 3-7 days after completion of treatment. Cultures should be obtained from the anal canal of all women who have been treated for gonorrhea.

### TREATMENT FAILURES

The patient who fails therapy with penicillin, ampicillin, amoxicillin, or tetracycline should be treated with 2.0 g of spectinomycin intramuscularly.

Most recurrent infections after treatment with the recommended schedules are due to *reinfection* and indicate a need for improved contact tracing and patient education. Since infection by penicillinase ($\beta$-lactamase)-producing *Neisseria gonorrhoeae* is a cause of treatment failure, posttreatment isolates should be tested for penicillinase production.

### NOT RECOMMENDED

Although long-acting forms of penicillin (such as benzathine penicillin G) are effective in syphilotherapy, they have NO place in the treatment of gonorrhea. Oral penicillin preparations such as penicillin V are not recommended for the treatment of gonococcal infection.

## Penicillinase-Producing *Neisseria Gonorrhoeae* (PPNG)

Patients with uncomplicated PPNG infections and their sexual contacts should receive spectinomycin, 2.0 g, intramuscularly in a single injection. Because gonococci are very rarely resistant to spectinomycin and reinfection is the most common cause of treatment failure, patients with positive cultures after spectinomycin therapy should be re-treated with the same dose.

A PPNG isolate that is resistant to spectinomycin may be treated with cefoxitin, 2.0 g, in a single intramuscular injection, with probenecid, 1.0 g, by mouth.

†Food and some dairy products interfere with absorption. Oral forms of tetracycline should be given 1 hour before or 2 hours after meals.

## Treatment in Pregnancy

All pregnant women should have endocervical cultures for gonococci as an integral part of the prenatal care at the time of the first visit. A second culture late in the third trimester should be obtained from women at high risk of gonococcal infection.

Drug regimens of choice are APPG, ampicillin, or amoxicillin, each with probenecid as described above.

Women who are allergic to penicillin or probenecid should be treated with spectinomycin.

Refer to the sections on acute salpingitis and disseminated gonococcal infections for the treatment of these conditions during pregnancy. Tetracycline should not be used in pregnant women because of potential toxic effects for mother and fetus.

## Acute Salpingitis (Pelvic Inflammatory Disease)

There are no reliable clinical criteria to distinguish gonococcal from nongonococcal salpingitis. Endocervical cultures for *N. gonorrhoeae* are essential. Therapy should be initiated immediately.

### HOSPITALIZATION

In the following situations, hospitalization should be strongly considered: uncertain diagnosis, in which surgical emergencies such as appendicitis and ectopic pregnancy must be excluded; suspicion of pelvic abscess; severe illness; pregnancy; inability of patient to follow or tolerate an outpatient regimen; or failure of patient to respond to outpatient therapy.

### ANTIMICROBIAL AGENTS

**Outpatients:** *Tetracycline**: 0.5 g, taken orally 4 times a day for 10 days. This regimen should not be used for pregnant patients; **OR**

*APPG*: 4.8 million units intramuscularly, ampicillin, 3.5 g, or amoxicillin, 3.0 g, each with probenecid, 1.0 g. Either regimen is followed by ampicillin, 0.5 g, or amoxicillin, 0.5 g, orally 4 times a day for 10 days.

**Hospitalized patients:** *Aqueous crystalline penicillin G*: 20 million units given intravenously each day until improvement occurs, followed by ampicillin, 0.5 g, orally 4 times a day to complete 10 days of therapy; **OR**

*Tetracycline**: 0.25 g, given intravenously 4 times a day until improvement occurs, followed by 0.5 g orally 4 times a day to complete 10 days of therapy. This regimen should not be used for pregnant women. The dosage may have to be adjusted if renal function is depressed.

Since optimal therapy for hospitalized patients has not been established, other antibiotics in addition to penicillin are frequently used.

### SPECIAL CONSIDERATIONS

Failure of the patient to improve on the recommended regimens does not indicate the need for stepwise additional antibiotics, but requires clinical reassessment.

The intrauterine device is a risk factor for the development of pelvic inflammatory disease. The effect of removing an intrauterine device on the response of acute salpingitis to antimicrobial therapy and on the risk of recurrent salpingitis is unknown.

Adequate treatment of women with acute salpingitis must include examination and appropriate treatment of their sex partners because of their high prevalence of nonsymptomatic urethral infection. Failure to treat sex partners is a major cause of recurrent gonococcal salpingitis.

Follow-up of patients with acute salpingitis is essential during and after treatment. All patients should be recultured for *N. gonorrhoeae* after treatment.

Note: Physicians are cautioned to use no less than the recommended dosages of antibiotics.

## Acute Epididymitis

Acute epididymitis can be caused by *N. gonorrhoeae, Chlamydia*, or other organisms. If gonococci are demonstrated by Gram stain or culture of urethral secretions, treatment should be APPG, 4.8 million units, ampicillin, 3.5 g, or amoxicillin, 3.0 g, each with probenecid, 1.0 g. Either regimen is followed by ampicillin, 0.5 g, or amoxicillin, 0.5 g, orally 4 times a day for 10 days; OR

Tetracycline*: 0.5 g, orally 4 times a day for 10 days.

If gonococci are not demonstrated, the above tetracycline regimen should be used.

## Disseminated Gonococcal Infection

### TREATMENT SCHEDULES

There are several, equally effective treatment schedules in the arthritis-dermatitis syndrome. These include the following.

**Ampicillin/amoxicillin:** ampicillin, 3.5 g, or amoxicillin, 3.0 g, orally, each with probenecid, 1.0 g, followed by ampicillin 0.5 g, or amoxicillin, 0.5 g, 4 times a day orally for 7 days; OR

**Tetracycline*:** 0.5 g, orally 4 times a day for 7 days. Tetracycline should not be used for complicated gonococcal infection in pregnant women; OR

**Spectinomycin:** 2.0 g, intramuscularly twice a day for 3 days (treatment of choice for disseminated infections caused by PPNG); OR

**Erythromycin:** 0.5 g, orally 4 times a day for 7 days; OR

**Aqueous crystalline penicillin G:** 10 million units intravenously per day until improvement occurs followed by ampicillin, 0.5 g, 4 times a day, to complete 7 days of antibiotic treatment.

### SPECIAL CONSIDERATIONS

Hospitalization is indicated in patients who may be unreliable, have uncertain diagnosis, or have purulent joint effusions or other complications.

Open drainage of joints other than the hip is not indicated. Intra-articular injection of antibiotics is unnecessary.

### MENINGITIS AND ENDOCARDITIS

Meningitis and endocarditis caused by the gonococcus require high-dose intravenous penicillin therapy. In penicillin-allergic patients with endocarditis, desensitization and administration of penicillin are indicated. Chloramphenicol may be used in penicillin-allergic patients with meningitis.

## Gonococcal Infections in Pediatric Patients

With gonococcal infections in children beyond the newborn period, the possibility of sexual abuse must be considered. Genital, anal, and pharyngeal cultures should be obtained from all patients before antibiotic treatment. Appropriate cultures should be obtained from individuals who have had contact with the child.

*Food and some dairy products interfere with absorption. Oral forms of tetracycline should be given 1 hour before or 2 hours after meals.

## Prevention of Gonococcal Ophthalmia

When required by state legislation or indicated by local epidemiologic considerations, effective and acceptable regimens for prophylaxis of neonatal gonococcal ophthalmia include ophthalmic ointment or drops containing tetracycline or erythromycin OR a 1% silver nitrate solution.

### SPECIAL CONSIDERATIONS

Bacitracin is not recommended. The value of irrigation after application of silver nitrate is unknown.

## Management of Infants Born to Mothers with Gonococcal Infection

The infant born to a mother with gonorrhea is at high risk of infection and requires treatment with a single intravenous or intramuscular injection of aqueous crystalline penicillin G, 50,000 units to full-term infants or 20,000 units to low-birth-weight infants. Topical prophylaxis for neonatal ophthalmia is not adequate treatment. Clinical illness requires additional treatment.

## Neonatal Disease

### GONOCOCCAL OPHTHALMIA

Patients should be hospitalized and isolated for 24 hours after initiation of treatment. Untreated gonococcal ophthalmia is highly contagious. Aqueous crystalline penicillin G, 50,000 units/kg/day, in 2 doses intravenously should be administered for 7 days. Saline irrigation of the eyes should be performed as needed. Topical antibiotic preparations alone are not sufficient or required when appropriate systemic antibiotic therapy is given.

### COMPLICATED INFECTION

Patients with arthritis and septicemia should be hospitalized and treated with aqueous crystalline penicillin G, 75,000 to 100,000 units/kg/day, intravenously in 2 or 3 divided doses for 7 days. Meningitis should be treated with aqueous crystalline penicillin G, 100,000 units/kg/day, divided into 3 or 4 intravenous doses, and continued for at least 10 days.

## Childhood Disease

Children who weigh 100 lbs. (45 kg) or more should receive adult regimens. Children who weigh less than 100 lbs. should be treated as follows.

### UNCOMPLICATED DISEASE

Uncomplicated vulvovaginitis, urethritis, proctitis, or pharyngitis can be treated at 1 visit with amoxicillin, 50 mg/kg, orally with probenecid, 25 mg/kg (maximum 1.0 g), OR with aqueous procaine penicillin G, 100,000 units/kg, intramuscularly plus probenecid, 25 mg/kg (maximum 1.0 g).

### SPECIAL CONSIDERATIONS

Topical and/or systemic estrogen therapy are of no benefit in vulvovaginitis. Long-acting penicillins, such as benzathine penicillin G, are not effective. All patients should have follow-up cultures, and the source of infection should be identified, examined, and treated.

### GONOCOCCAL OPHTHALMIA

Ophthalmia in children is treated as in neonates, but the dose of penicillin is increased to 100,000 units/kg/day intravenously.

### COMPLICATED INFECTIONS

Patients with peritonitis or arthritis require hospitalization and treatment with aqueous crystalline penicillin G, 100,000 units/kg/day, intravenously for 7 days. Aqueous crystalline penicillin G, 250,000 units/kg/day, intravenously in 6 divided doses for at least 10 days, is recommended for meningitis.

### ALLERGY TO PENICILLINS

Children who are allergic to penicillins should be treated with spectinomycin, 40 mg/kg, intramuscularly. Children older than 8 years may be treated with tetracycline, 40 mg/kg/day, orally in 4 divided doses for 5 days. For treatment of complicated disease, the alternative regimens recommended for adults may be used in appropriate pediatric dosages.

# AMERICAN ACADEMY OF PEDIATRICS

Committee on Drugs
Committee on Fetus and Newborn
Committee on Infectious Diseases

## Prophylaxis and Treatment of Neonatal Gonococcal Infections

The Center for Disease Control (CDC), after consultation with a panel of experts, has revised its recommendations for prevention of gonococcal ophthalmia neonatorum. These recommendations now state, "ophthalmic ointment or drops containing tetracycline or erythromycin or a 1% silver nitrate solution" are effective and acceptable.[1-3] This is a change from previous recommendations which highlighted silver nitrate as the primary agent for prophylaxis.[4] The American Academy of Pediatrics' committees support these recommendations.

The prevalence of largely asymptomatic genital gonococcal infection in pregnant women and the occurrence of gonococcal ophthalmia in untreated infants (estimated at 28%)[5] born to infected women indicate the need for continued prophylaxis for all newborn infants.

Some clinicians have argued that silver nitrate prophylaxis immediately after delivery may, in theory, impair maternal-infant bonding by reducing eye contact.[6,7] Although it is well-known that silver nitrate, with or without subsequent flushing, results in a high frequency of chemical conjunctivitis,[8,9] other agents, particularly ointments, may also impair vision temporarily and affect the appearance of the infant.

In view of the available information about the prophylaxis of gonococcal ophthalmia neonatorum and treatment of infected infants, the American Academy of Pediatrics makes the following recommendations:

1. A 1% silver nitrate solution in single-dose ampules or single-use tubes of an ophthalmic ointment containing 1% tetracycline or 0.5% erythromycin are effective and acceptable regimens for prophylaxis of gonococcal ophthalmia neonatorum.

2. None of the agents used for prophylaxis should be flushed from the eye following instillation. Critical studies have not evaluated the efficacy of silver nitrate prophylaxis with and without flushing, but anecdotal reports suggest that flushing may reduce the efficacy of prophylaxis. In addition, flushing probably does not reduce the incidence of chemical conjunctivitis.[5]

3. Prophylaxis should be given shortly after birth. No studies have evaluated the effect of delaying prophylaxis on its efficacy. Some authors suggest prophylaxis may be administered more effectively in the nursery than in the delivery room.[10] Although definitive data are not available, delaying prophylaxis for up to one hour after birth probably will not affect efficacy and should facilitate initial maternal-infant attachment. *Hospitals in which prophylaxis is delayed should establish a check system to ensure that all infants are treated.*

4. Infants born by cesarean section should also receive prophylaxis against gonococcal ophthalmia. Although gonococcal infection is usually transmitted during passage through the birth canal, ascending infection also occurs. However, the precise risk of gonococcal infection in untreated infants born by cesarean section has not been determined.

5. Most infants born to mothers with clinically apparent gonorrhea are prevented from developing gonococcal ophthalmia with current modes of prophylaxis. However, an occasional case of gonorrheal ophthalmia may occur in such infants.[5,11-13]

Therefore, intravenous or intramuscular aqueous crystalline penicillin G should be administered to these infants. A single dose of 50,000 units for term or 20,000 units for low-birth-weight infants is rec-

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ommended. Topical prophylaxis alone is inadequate for these infants.

6. Infants with clinical evidence of ophthalmia or complicated (disseminated) gonococcal infection should be hospitalized under isolation and treated appropriately. Because gonococcal ophthalmia is highly contagious, infected infants must be managed with either wound and skin precautions[14] or secretion precautions[15] for 24 hours after initiation of treatment with aqueous crystalline penicillin G, 50,000 units/kg body weight daily in two doses intravenously for seven days. The eyes should be irrigated with saline. Topical antibiotics are superfluous when appropriate systemic antibiotic therapy is given. Ophthalmologic consultation is suggested. Infants with extraocular gonococcal infections such as arthritis or septicemia, should be treated with aqueous crystalline penicillin G, 75,000 to 100,000 units/kg body weight daily in two to three doses intravenously for seven days. Infants with gonococcal meningitis should also be treated with aqueous crystalline penicillin G, 100,000 units/kg body weight daily in three to four doses intravenously for at least ten days. Note: The emergence of strains of *Neisseria gonorrhoeae* resistant to penicillin must be recognized. Attempts should be made to isolate the organism from the mother and the child so antibiotic sensitivity can be determined. If other forms of antimicrobial therapy become necessary because of a poor clinical response to penicillin, these sensitivities would be available as a therapeutic guide.

7. Gonococcal infections in pregnant women, even though they are asymptomatic, may be associated with fetal wastage, early and prolonged rupture of membranes, premature labor, and delivery of low-birth-weight infants.[11,16] They also may result in sepsis or scalp abscess if intrauterine fetal monitoring is used.[12,13] Failure to treat an infected woman before or at the time of delivery may result in transmission of gonococcal infection postnatally to infants who escape infection at delivery.


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Attachment #5

CENTER FOR DISEASE CONTROL

# MMWR

MORBIDITY AND MORTALITY WEEKLY REPORT

March 31, 1978 / Vol. 27 / No. 13

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## *Current Trends*

### Silver Nitrate Prophylaxis for Gonococcal Ophthalmia Neonatorum

The National Society for the Prevention of Blindness and the American Academy of Pediatrics have stated in recent years that infants' eyes should *not* be irrigated after instillation of 1% silver nitrate ($AgNO_3$) (*1,2*). The package insert from the drug manufacturer also states that irrigation (usually done with normal saline or distilled water) is not recommended.

Maine's Department of Human Services--noting that many hospitals are irrigating infant's eyes, apparently to minimize the chemical conjunctivitis caused by $AgNO_3$—conducted a survey in March 1977 to determine how widespread this practice is. The nursery or delivery suite supervisor was contacted by telephone in all Maine hospitals that deliver babies. Of 44 hospitals 23 (52%) still used irrigation; 11/44 (25%) specified that they had no definite policy on this matter. Thus, 10/44 (23%) of hospitals were acting according to present recommendations. The survey also revealed that a few hospitals routinely used penicillin ophthalmic solutions instead of $AgNO_3$, although the latter is required by Maine law. After the survey a letter was circulated to hospitals to correct the practices.

*Reported by K Hill, MD, Waterville; E Johnson, WS Nersesian, MD, Acting State Epidemiologist, Maine Dept of Human Services; Clinical Research Sect, Venereal Disease Control Div, Bur of State Services, CDC.*

**Editorial Note:** The chemical conjunctivitis caused by $AgNO_3$ drops is self-limiting, usually resolving within 24-48 hours. It is less severe if the drops are stored in individual wax ampules. This procedure minimizes evaporation, which would increase the concentration of the solution.

CDC's gonorrhea treatment recommendations include the use of $AgNO_3$ without saline rinse for all newborn infants (*3*). $AgNO_3$ prophylaxis appears to be more effective in preventing gonococcal ophthalmia neonatorum (GC-ON) than saline eye washings or no prophylaxis (*4-7*). $AgNO_3$ prophylaxis is not 100% effective, however, as shown in 1 study of 46 cases of gonococcal ophthalmia which occurred in spite of some form of $AgNO_3$ prophylaxis (*8*). Nevertheless, according to that study the risk of GC-ON developing in an infant born to an infected mother was less than 2% when $AgNO_3$ was used.

The occurrence of GC-ON in spite of the use of $AgNO_3$ may be caused by several factors: (1) improper application, (2) washing with water or saline, (3) silver cation precipitation by saline to form silver chloride crystals, (4) infection of the eyes before delivery because of premature rupture of the membranes in an infected woman, and (5) failure to treat an infected mother with subsequent transmission to her infant after the delivery.

Well-designed studies are needed to investigate other preparations which may be useful as prophylaxis against GC-ON. Other possibly effective agents have either not been adequately studied (tetracycline and erythromycin), are less effective (bacitracin), or have serious adverse effects, such as sensitization (penicillin). The possibility of infection with a penicillinase-producing gonococcus also exists.

In addition to proper instillation of $AgNO_3$ without rinsing, other measures are essential in preventing GC-ON, including: (1) prenatal screening of pregnant women at their initial visits and before delivery, (2) appropriate evaluation of all neonatal conjunctival discharges with Gram stain and culture, and (3) continuing education for obstetric and pediatric personnel who will be required to diagnose and manage this complication.

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Published in MMWR 17:171, 1968; reprinted 18(43 Suppl):14, 1969; revised 21(25 Suppl): 19-20, 1972.

## *Current Trends*

### Clarification: Silver Nitrate Prophylaxis for Gonococcal Ophthalmia Neonatorum

Following the publication of an article in the MMWR entitled, "Silver Nitrate Prophylaxis for Gonococcal Ophthalmia Neonatorum," several inquiries have been directed to CDC regarding a statement in the editorial note (*1*). The sentence (in the second column, second paragraph), which concerned the need for investigation of prophylactic preparations against gonococcal ophthalmia neonatorum, read: "Other possibly effective agents have either not been adequately studied (tetracycline and erythromycin), are less effective (bacitracin), or have serious adverse effects, such as sensitization (penicillin)." It should be changed to read: "Other agents for topical eye prophylaxis have either been less adequately studied (tetracycline and erythromycin), are less effective (bacitracin), or may cause sensitization (penicillin or neomycin)."

No proven cases of penicillin anaphylaxis in newborns from either topical or systemic administration of the drug have been reported to CDC. Sensitization of newborns by penicillin or neomycin eye prophylaxis is a distinct but unproven possibility.

*Reported by the Venereal Disease Control Div, Bur of State Services, CDC.*

*Reference*

1. MMWR 27:107, 1978

### Erratum, Vol. 27, No. 25

p214 In the article, "Malaria in Participants of a Natural History Safari to Kenya, Africa," the 10th line of the first paragraph of the editorial note indicated that the weekly dose of chloroquine used for malaria prophylaxis is 550 mg. The correct figure is 500 mg.

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STATE OF MINNESOTA

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BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the
Proposed Amendments
to Mn. Rule MHD 326(o)
Relating to Prophylaxis
for Opthalmia Neonatoram

CERTIFICATE OF
COMPLIANCE WITH
RULEMAKING PROCEDURES

I, Special Assistant Attorney General Terry P. O'Brien, do hereby declare that I have examined the above-captioned rule and all related documents and that, based on my examination and my personal familiarity with the applicable procedures, the Administrative Procedure Act, and the rules of the Office of Administrative Hearings, and the rules of the Attorney General have been followed without any exceptions.

Dated: March 25, 1982

TERRY P. O'BRIEN
Special Assistant
Attorney General

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

In the Matter of the
Proposed Amendments
to Mn. Rule MHD 326(o)
Relating to Prophylaxis
for Opthalmia Neonatoram

AFFIDAVIT

STATE OF MINNESOTA )
) ss.
COUNTY OF HENNEPIN )

George R. Pettersen, being first duly sworn upon oath, deposes and says:

1. That on January 11, 1982, a Notice of Intent to Adopt Rules Without a Public Hearing was published in the State Register and on December 31, 1981, the same Notice was mailed to persons who have requested to be informed of rulemaking activity by the Minnesota Department of Health.

2. That to date no one has requested a rule hearing, no one has submitted any comments on the rule, nor has anyone requested to be informed of submission of the rule to the Attorney General's office for review as to form and legality.

FURTHER AFFIANT SAYETH NOT.

Dated: March 22, 1982

George R. Pettersen M.D.

GEORGE R. PETTERSEN, M.D.
Commissioner of Health

Subscribed and sworn to before me
this 22 day of March, 1982.

Louise K. Kaniuk

LOUISE K. KANIUK
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HENNEPIN COUNTY
My Comm. Expires Feb. 23, 1984