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Is North Dakota Premarital Law Requiring Syphilis Serologies Justifiable?

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IS NORTH DAKOTA'S PREMARTIAL LAW REQUIRING SYPHILIS SEROLOGIES JUSTIFIABLE?

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TABLE OF CONTENTS

CHAPTER I

THIS STUDY: WHAT IT'S ABOUT

Public administration is an interdisciplinary field of study that deals with such disciplines as business administration and management, law, economics, psychology, sociology and anthropology, and political science.[1] This study is related to public administration in almost all of these areas, and will investigate a law.

The Purpose

The law under investigation is North Dakota's premarital law with the purpose of justifiability. This is not a study to decide whether a new law should be put on the books, but rather, it is a study to decide whether a law already on the books should remain there or be abolished.

The Problem

In order to determine whether or not the law is justifiable, criteria must be developed. Two sets of criteria will be used.

The general evaluation criteria will include benefit-cost analysis, cost effectiveness, and comparison evaluation to test justifiability.

The specific criteria for evaluation of justifiability include

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[1]Robert D. Pursley and Neil Snortland, Managing Government Organizations (Massachusetts: Duxbury Press, 1980), p. 14.

the laws goals, its legal requirements, costs, and outcomes.

The Hypothesis

My experience at the North Dakota State Department of Health, Public Health Laboratory leads me to use the null hypothesis as my working hypothesis. The hypothesis is that North Dakota's premarital law is not justifiable.

In testing this hypothesis, this study will use surveys, literature comparisons, evaluation techniques, and records in the Health Department.

The Importance

This study is relevant to public administration as was previously mentioned. It is also important because of its involvement of state bureaucracy in the administration of the law, the legislature because it is their responsibility to make law, and the public, those individuals who desire to marry in this state because they must comply with the law and bear the costs which come along with it.

CHAPTER TWO

DATA, DATA ANALYSIS, AND METHODOLOGY

To more fully understand the premarital law requiring syphilis testing and the reasoning for or against it, it is necessary that background information be given about syphilis.

Syphilis And History

Where syphilis began or came from is not completely known.

One theory concerning the orgin of syphilis is the Columbian theory. Some skeletal evidence suggests it began in South American Indians before the time of Columbus. Syphilis was believed to not exist elsewhere in the world until shortly after the return of Christopher Columbus from his first voyage to the New World, and first showing up in the known world in Naples. Many Spanish sailors who contracted syphilis from voyages to the West Indies joined the army of the French King for the invasion of Naples in 1494. These men eventually transmitted the disease to many camp followers and residents of the city, and syphilis, in the end, overtook the French army.

In 1495, after the fall of Naples, for the next fifteen years the disease was spread throughout the known world. Medical historians estimate that millions of individuals contracted the disease during that time. In France, the disease was first known as the Neapolitan disease, whereas in Naples it was called the French sickness. In 1530, the

disease came to be called syphilis when Girolamo Fracastoro wrote his epic poem Syphilis sive Morbus Gallicus. The main character in his poem being a shepherd named "Syphilus."

The causative organism for syphilis was not discovered until 1905, however it could be diagnosed through its symptoms. German bacteriologists Fritz Schaudinn and Erich Hoffmann first observed the organism which caused syphilis, but only after the development of the dark-field microscope.

August von Wassermann, a German bacteriologist, developed the first blood test for the detection of syphilis in 1907. Shortly after this, in 1910, salvarsan, or 606, an arsenic compound was introduced by yet another German scientist Paul Ehrlich as the first drug for syphilis. Salvarsan was found to have its shortcomings, and in 1931 it was learned that the drug could be more effective when used in conjunction with bismuth. This method of treatment required thirty bimonthly injections of salvarsan interspersed with forty injections of bismuth. Many people died from the disease because the regimen of treatment was too unbearable for them.

In 1928, the British bacteriologist Alexander Fleming discovered penicillin, the first specific cure for syphilis. This drug was not used to cure syphilis though until 1943 when John Mahoney and the staff of the U.S. Public Health Service Hospital on Staten Island, New York, were seeking an answer to the growing problem of syphilis control. Penicillin treatment of syphilis reached a high level of effectiveness in the early 1950's through research and experimentation. Penicillin is still the drug of choice today, but antibiotics such as erythromycin and tetracycline are also effective.

The origin of syphilis as mentioned at the beginning of this chapter has been disputed by some individuals. Other evidence from skeletons suggest that syphilis was in the known world long before the sailors of Columbus brought it back from the West Indies. Some bone studies of skeletons suggest that it was around in Biblical times, and what was thought to have been leprosy in many cases may have been syphilis in fact.

Syphilis The Disease

The organism causing syphilis is called Treponema pallidum and is a spiral type bacteria which are unicellar organisms. The spirochete can be destroyed by exposure to disinfectants, soap, and heat, and is an anaerobic organism and therefore only lives in places where there is no air.

The syphilis causing spirochetes are most often introduced in anal, genital or oral regions of the body during sexual contact, they may however enter the body through any mucous membrane or skin abrasion. Following inoculation there is a ten day to ten week (usually three weeks) incubation period. During this period, the organisms are being carried deep into the body tissues and organs by the blood and lymphatic systems without signs or symptoms.

Early signs of the disease can usually be seen after the incubation period. The first sign of disease is usually a lesion called a chancre, which is the beginning of the stage known as primary syphilis. Individuals may fail to develop a lesion or the lesion may not resemble a typical chancre of syphilis. This chancre appears at the site where the organism is introduced into the body, and is very infectious. This chancre may be concealed in women because the cervix and vagina are the

most common infection sites, and in homosexual males because the rectum is the most common site. These individuals are highly infectious, and since the chancre is painless, they are unaware of infection. The chancre will disappear spontaneously in a matter of days or weeks.

Several weeks after the chancre disappears, the signs and symptoms of the secondary stage appear. These signs and symptoms vary from fever, and malaise to the swelling of various lymph nodes.

The most common lesions characteristic of the secondary stage appear on the skin and mucous membranes. These lesions may very greatly. They may be blotches,bumps, scales, or moist looking welts or bumps, whitish patches in the mouth and throat and other mucous membranes as well as patchy falling hair and inflammation of the eyes and throat may also be secondary syphilis. These secondary lesions are also highly infectious and will disappear without treatment. They may however reoccur from time to time up to the second year of infection.

The period following the second stage of syphilis or between secondary stages is known as the latent period. This period may last several years and has characteristically no signs or symptoms, and can only be diagnosed by serology tests.

Symptoms may reappear after a period of time marking the beginning of the stage called late symptomatic syphilis. This stage is characterized by two types of damage: chronic, highly destructive, but localized damage to the skin, bones and visceral organs, and generalized damage to the heart or central nervous system, the brain and spinal cord. With the exception of pregnant women, who can transmit the disease to their unborn babies, most individuals are not infectious after the last appearance of the secondary lesions.

When a woman with syphilis becomes pregnant, her baby will be infected unless the mother is treated before the 18th week of pregnancy. After this time the spirochetes will pass through the placenta to the developing fetus. Treatment of the pregnant woman almost always cures the fetus. If treatment is started very late in pregnancy though, the baby may be near death and not respond to treatment.

Early congenital syphilis (syphilis in children under the age of two) often causes blistery skin or mucous membrane lesions, bone damage, enlargement of the liver and spleen, kidney disease, anemia, pneumonia and meningitis.

Late congenital syphilis (syphilis in children after the age of two) may cause eye damage only to be blind upon reaching adolescence, tooth bud damage, deafness, neurosyphilis, and destructive lesions of the skin, bones, and visceral organs.

In diagnosing syphilis, the patients history of exposure, and signs and symptoms are importnat. Laboratory serology (blood) tests are used, and if lesions are found, a dark-field examination for spirochetes may be done.

Blood tests, or serology tests, are generally of two types.

One type of test, tests for the presence of an antibody like substance called reagin and is a nontreponemal test. In theory, this substance results from the reaction of treponemes on body tissues. Other disease states may however also produce reagin and these tests may not entirely be specific for syphilis. Because of their sensitivity, ease of performance and low cost, this type of test is widely used as a screening procedure.

The other type of syphilis serology test is a treponemal antibody

test. These treponemal tests are more specific than the nontreponemal tests because unlike reagin, specific antibodies from an individual are reacted in certain ways with actual treponemes. Nowadays these treponemal tests are almost always used to confirm a positive, and sometimes negative, nontreponemal test.

North Dakota's Premarital Law: What Is It

North Dakota's premarital law covers a variety of areas. As shall be seen from the Century Code, it covers such areas as: the public's requirement to be tested for syphilis before a marriage license is issued to them; what state entity is responsible for the testing; certificate contents; exceptions to the premarital testing; penalties for failure to follow the regulations concerning the physician's certificate and laboratory statement.

The following is North Dakota's premarital law from the North Dakota Century Code Replacement Volume 3A, Chapter 14-03 Marriage Contract, sections 14-03-12 up to and including 14-03-16 as they relate to this study.

> 14-03-12. SEROLOGICAL TEST FOR SYPHILIS REQUIRED BEFORE APPLICATION FOR LICENSE FILED. Before any county judge shall accept an application for a marriage license, each applicant must file with him a certificate from a duly licensed physician and surgeon stating that the applicant has been given a standard serological test and such other examination as may be necessary for the discovery of syphilis, and that in the opinion of the physician and surgeon the applicant is not infected with syphilis or that if so infected such disease is not is such a stage of development that it is or may become communicable to the marital partner. Such examination shall have been made not more than thirty days prior to the date of the application. No license shall be granted if either party is infected with syphilis or other venereal disease in communicable form, and no person who is so afflicted is entitled to marry.
>
> 14-03-13. "STANDARD SEROLOGICAL TEST" DEFINED. A standard serological test shall be a laboratory test for syphilis approved by the state health officer and shall be performed by the state department of health, or by any other laboratory approved by the state health officer. The county judge shall collect a fee of not to exceed fifty cents for each serological test performed in this state, which shall be paid by him into the state treasury on the first day of July. The fee shall be collected from each applicant for a marriage license upon whom the test has been performed. State public health laboratories outside of the state of North Dakota which have been approved by the state health officer shall make their own arrangements

as to the amount and manner of collecting their fees for the service.

14-03-14. SEROLOGICAL TEST - CONTENTS OF LABORATORY STATEMENT. The certificate of the physician and surgeon shall be accompanied by a statement from the person in charge of the laboratory making the test, or from some other person authorized to make the statement. The statement shall set forth the name of the test, the date it was completed, and the name and address of the person whose blood was tested. It shall not state the result of the test. The physician's certificate and the laboratory statement shall be on the same form sheet. A detailed report of the laboratory test showing the result of the test shall be transmitted by the laboratory to the physician and surgeon, who shall file it with the state health officer, where it shall be held in absolute confidence and shall not be open to public inspection. Upon order of a judge of a court of competent jurisdiction, it shall be produced as evidence in a proceeding involving issues in which it is material and relevant. Nothing in this section shall affect the duty of physicians and others to report cases of syphilis discovered by them.

14-03-15. WHEN SEROLOGICAL TEST NOT NECESSARY. In case of emergency or other cause shown by affidavit or other proof, the judge of the district court may make an order, on joint application of both parties, dispensing with the requirement for filing with the county judge the physician's certificate and the laboratory statement, or he may extend the time in which such examination shall have been made to not more than ninety days, if he is satistied that neither the health of the individuals nor the public health and welfare will be affected injuriously. The order shall be accompanied by a memorandum from the district judge reciting his reasons for granting the order. Applications for extensions may be made before or after the expiration of the thirty-day period. The order and accompanying memorandum shall be filed with the county judge and he shall accept the application for the marriage license without the filing of the physician's certificate and the laboratory statement, or he shall accept the application within the extended period, as the case may be. The county judge and his clerk and employees shall hold the memorandum of the district judge in absolute confidence.

14-03-16. PHYSICIAN'S CERTIFICATE AND LABORATORY STATEMENT-MISREPRESENTATION-PENALTY. Any person who shall misrepresent any of the facts called for by the physician's certificate and the laboratory statement, any licensing officer who shall accept an application for a license without the physician's certificate and laboratory statement unless they have been dispensed with by order of the district court, or who has reason to believe that the facts contained in said statements have been misrepresented and nevertheless issues a license, any health officer who shall not hold the laboratory record confidential, and any

> officer, clerk, or employee of the office issuing the license who shall not hold in strict confidence the statement of the district judge in granting the judicial order, shall be punished as provided in section 14-03-28.

North Dakota's Premarital Law: History Of The Law

North Dakota's premarital law dates back to 1939. According to the North Dakota Legislative Council, no legislative records on the original law are on file, however through conversations with individuals from the health department who were around at the time of the law, some personal information (a very small amount) was available.

According to Ken Mosser, the director of the Division of Disease Control with the North Dakota State Department of Health, North Dakota's premarital law is a result of a national push by the Federal Public Health Service of the United States in the latter part of the 1930's with the objective of syphilis control, especially congential syphilis.

Even without any written history of the law, information from "Syphilis And History", and "Syphilis The Disease" can be put together to understand the reasoning behind the law or the push by Federal Public Health Service for the law.

Syphilis is a venereal disease that is spread from one person to another and is therefore a communicable disease. So, stopping the spread of a communicable venereal disease is one objective. In 1943, penicillin was first used by the U.S. Public Health Service for syphilis, but it didn't become readily available until the late 1940's and early 1950's for general use. In 1939, North Dakota's premarital law was put on the books. The law would not only be to control a communicable venereal disease, but one almost uncurable, considering the effectiveness of salvarsan-bismuth. The control of a disease that could effect skin, bone,

viscera, central nervous system and cardiovascular systems and even cause death is important, not to mention institutionalization probabilities. During the time this law was initiated (1939) the syphilis case rate was 57.3 per 100,000 for North Dakota and in 1981, it stands at only 2.9 per 100,000.[2]

What about congenital effects? With no real cure, virtually a variety of unknown damaging effects are possible and guaranteed to offspring. (See "Syphilis The Disease.")

It is important, also to consider that social expectations of this period (1930's and 1940's) was that when young individuals married, a family was begun early in the marriage, usually in the first year.[3]

The serological test was chosen because it can detect all the stages of syphilis, and is sensitive and low in cost.

What Does The Law Require: Public Requirements

The premarital mandate of North Dakota requires that each individual who plans to marry in the state must have a syphilis serology test performed.

Section 14-03-12 of the North Dakota Century Code requires that the applicants for marriage license have in their possession, even before they apply for the marriage license, the certificate from a physician,

> "stating that the applicant has been given a standard serological test and such other examination as may be necessary for the discovery of syphilis, and that in the opinion of the physician and surgeon the applicant is not infected

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[2]N.D. State Department of Health, Disease Control, Bismarck.

[3]Yehudi M. Felman, MD, "Laws Mandating Premarital Serologic Tests for Syphilis Should be Repealed," Archives of Dermatology, Vol. 118, March 1982, p. 145.

with syphilis or that if so infected such disease is not in such a stage of development that it is or may become communicable to the marital partner."[4]

This mandate in requiring all individuals to have a syphilis test performed has hidden requirements as well. The hidden requirements include such things as transportation to and from a physician and/or a clinical laboratory that performs a syphilis serology test, the cost for the serology test and the physician's certificate, and perhaps even a physical examination in certain instances. The law requires that applicants pay out dollars for testing to get married.

Not only do those applicants who desire to marry in North Dakota need a test, but it cannot be completed more than thirty days prior to the date of the application.

This thirty day time period is questionable as can be shown by one example. An individual, a young male, was tested for syphilis as proscribed by the law, and was found to be negative for syphilis. In a weeks period before the marriage, various activities were held, and the individual, because of the activities, contracted syphilis from one of his five contacts.

The last sentence of Section 14-03-12 states that "No license shall be granted if either party is infected with syphilis or other venereal disease in communicable form, and no person who is so afflicted is entitled to marry."[5] This seems contradictory, since those with gonorrhea, herpes, chancroid, granuloma inguinale and other venereal diseases may marry.

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[4] North Dakota Century Code, Replacement Volume 3A, Chapter 14-03 Marriage Contract.

[5] Ibid.

Why aren't there standard tests for premarital testing mandated for these as well? In North Dakota, syphilis cases are fewer than gonorrhea or herpes. Herpes is uncurable and is capable of causing birth defects whereas syphilis is curable.

What Does The Law Require: Government Requirements

Perhaps Section 14-03-13 of the Century Code has the greatest ramifications for government requirements. The State Health Council, with its authority, has set up rules and regulations to enumerate this section. This section and the rules and regulations associated with the section pertain to the North Dakota State Department of Health.

Under the Rules and Regulations, R 14-03-01 A, places the responsibility of establishing rules and regulations for syphilis serology testing of premarital and prenatal requirements under the Health Department. Along with this responsibility, the Health Department must also approve any laboratory in the state which seeks approval to perform syphilis serologies for premarital and prenatal mandates, as well as provide consultation and training services.

Section R 14-03-01 B, sets up the minimal requirements necessary for a laboratory in the state to fulfill before approval. In other words the approval is conditional upon the requirements. These requirements include proficiency testing standards, on-site visits by a representative of the Division of Laboratories, minimum volume testing standards, and an agreement to send any positive syphilis test samples to the Public Health Laboratory (Division of Laboratories) for confirmation and disease control purposes.

Since the approval is conditional, any failure to meet the minimum

requirements results in a denial as in R 14-03-02.

R 14-03-03, R 14-03-04, and R 14-03-05, deal with approval levels from provisional approval to full approval to renewals. It is the Public Health Laboratory that must administer these approvals as well.

All individuals approved and their laboratories are published at least annually by the Public Health Lab and mailed to all clinical laboratories and county judge offices in the state as put forth in R 14-03-06. (See the Appendix, "List of Approved Labs.")

Section R 14-03-07, sums up the laboratories which are acceptable or approved to do syphilis premarital and prenatal testing as those which are approved by the methods in the rules and regulations, any state public health laboratory and the laboratories which they approve, as well as Armed Forces clinical laboratories and U.S. Public Health Service Laboratories.

The next section, R 14-03-08, sets up the minimum standards for the Public Health Laboratory to use for approval. These include personnel qualifications for individuals who will do the testing, quality assurance standards, and equipment and supplies necessary.

The final section, R 14-03-09, grants to any applicant the right of appeal for an administrative hearing, and a district court hearing. The appeal rights coming from the "Administrative Agencies Practice Act" of the North Dakota Century Code. (See the Appendix under "Rules Regulations.")

From the Century Code, Section 14-03-13, requires payment into the state treasury, by each county judge, the sum of fifty cents for each serology test performed, which adds up to a county administrative government requirement which probably costs more to carry out than the fee itself.

Section 14-03-04 requires that certain criteria be met for the contents of laboratory statements for the testing of syphilis, and that these be filed, by the physician, with the Health Department. This section not only requires the physician to file the laboratory results, but to have the state manage these records.

The judicial system is required to make judgment in Section 14-03-15. More specifically, the district judge is required to rule when a serological test is not necessary.

The last section, 14-03-16, requires that penalities by the State be incorporated for misrepresentation and confidentiality as they relate to the physicians certificate, the laboratory statement, and the marriage license.

Where Do Others Stand On Premarital Mandates: States Survey

When the U.S. Public Health Service put on its push for premarital laws, it was in all states, and not just in North Dakota. As a matter of fact, most states at some time have had a premarital mandate for syphilis serologies. A change is now taking place among states to abolish premarital syphilis requirements.

No standard test for syphilis is required, as of July 24, 1982, in the following list of states.[6,7]

Colorado
Delaware
Idaho
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Michigan
Minnesota
Nevada
New Hampshire
North Carolina
Ohio
South Carolina
Utah
Washington (State)
Wisconsin

Why are these states repealing or abolishing their premarital syphilis serologies? The main reason, is that the law is not doing what it was intended to do. They are not the best means to syphilis control.

One recent example of this is Delaware. In a news letter by the State of Delaware Department of Health and Social Services, a short editorial for repealing their premarital law was given, and the editorial is as follows.

"The Premarital Law was enacted in Delaware in 1953 to prevent and control syphilis, particularly congenital syphilis, in the newborn.

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[6]Kenneth F. Girard, Ph.D., Lab News, Massachusetts State Laboratory Institute, Issue #82:2, p. 9.

[7]Lab-O-Rator, State of Delaware, Department of Health and Social Services, Division of Public Health, Volume VII, No. 3, September 1, 1982, p. 2.

> The repeal of the law in no way indicated or assumes that syphilis is no longer a threat. Cases of infectious syphilis continue to be diagnosed in Delaware although no cases of public health significance, congenital or otherwise, have been found in premarital testing program during the past 10 years. Congenital syphilis is completely preventable. Its development can be related to two factors, when the pregnant woman becomes infected, and how long she remains infected. Detection of untreated syphilis before delivery and prompt therapy can often prevent congenital infection and can usually prevent complications among fetuses infected in utero.
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> Congenital syphilis can be eliminated or greatly reduced by: (1) preventing the spread in the heterosexual community through rapid diagnosis and through epidemiologic investigations; (2) educating females at risk of infection about the need to seek early and continuous prenatal care; and (3) encouraging medical care providers to perform serologic tests for syphilis on patients in the third, as well as the first trimester. Prenatal testing for syphilis is required by law in Delaware."[8]

Where Do Others Stand On Premarital Mandates: North Dakota Bureaucrats

The following was a survey to find out whether or not there is agreement among Health Department officials concerning views of the premarital syphilis serology law. This was a telephone survey, and included only those division directors who are closely associated to the law and are required to act under it in some way. These individuals were asked their opinion(s) on the premarital law as to whether it should be abolished or not, and their main reason for their opinions.

The survey included:

Disease Control Division Director
Laboratory Services Chief
Microbiology & Immunology Director
Training & Consulation Director

Each of the individuals expressed the same concern that the law was

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[8] Lab-O-Rator, State of Delaware, Department of Health and Social Services, Division of Public Health, Volume VII, No. 3, September 1, 1982, p. 2.

not justifiable because of the lack of productivity and related monetary costs.

Where Do Others Stand On Premarital Mandates: Center For Disease Control

In the U.S. Public Health Service, the main center for syphilis studies is at the Center for Disease Control in Atlanta, Georgia.

A one page letter for information was sent to the Chief of their venereal Disease Research Branch, and contained a few general questions relating to premarital syphilis serologies. The main purpose of the letter was to find out the view held by the Federal Government concerning the issue of repealing these laws. From the Center for Disease Control's response, it can be gathered that they are not strictly for or against premarital mandates but rather that all areas be investigated before a decision is finalized. (See the Appendix for the "CDC Letter" and "CDC Response".)

Where Do Others Stand On Premarital Mandates: The Literature Survey

Not many literature sources were available concerning premarital syphilis laws, not even through Medline the computer service. All of the available articles do complement each other quite well though and are incorporated into this study. Because they are incorporated, no further discussion of them will be undertaken. (See the Bibliography for these sources.)

The Costs Of The Law: How Much Does It Cost Survey

From the list of approved laboratories published by the Public Health Laboratory, a survey was carried out for premarital syphilis testing costs for use in statistical inferences. (See the Appendix under "List of Approved Labs".)

All thirteen laboratories approved in the state had cost questionnaires mailed to them. Of these thirteen laboratories, eleven answered and returned the survey for a response rate of 85%. The survey contained a self addressed, stamped, return enevelope.

The survey was a one page questionnaire and consisted of a short introduction, directions, and five cost questions. The questions were set up with the purpose of finding individual costs as they relate to the steps in syphilis testing. The steps are: to draw the blood specimen, perform the syphilis serology test, and get the certificate signed by a physician. The questionnaire not only tried to get costs from individual steps, but also from combinations of steps. The Appendix shows the survey questionnaire used. (See "Lab Survey Questionnaire" in Appendix.)

The following are tabulations from the cost survey questionnaire, and give the least amount charged for a service from all laboratories responding, the greatest amount charged for a service from all responding laboratories, and the average charge for a service for each question.

First Question. What is the dollar amount charged by your institute to only draw the blood sample for the premarital syphilis serology test?

Least amount	$ 3.70
Greatest amount	$10.00
Average	$ 5.95

Second question. What is the dollar amount charged by your institute to only test a premarital blood sample for syphilis?

Least amount	$ 2.00
Greatest amount	$13.00
Average	$ 6.75

Third question. What is the dollar amount charged by your institute to both draw the blood sample and test it for syphilis?

Least amount	$ 6.00
Greatest amount	$13.00
Average	$ 8.04

Fourth question. What is the dollar amount charged by your institute to only have a physician sign the premarital form?

This question had no response from any of the laboratories surveyed.

This non-response has two possible explanations, either the question was not clear enough, or there were no individual charges for this service. After a local telephone survey of approved labs in Bismarck, it was concluded that it was because there were no individual charges for this service at the approved labs. There was no charge because the physician who is head of the laboratory signed all certificates if negative and considered this as part of the laboratory testing cost.

Fifth question. What is the dollar amount charged by your institute to have the blood drawn, tested, and the premarital form signed by a physician at your institute?

Least amount	$ 7.00
Greatest amount	$13.00
Average	$ 8.55

Minot Air Force Base Hospital was excluded from these tabulations because they do not charge for syphilis serology work, and they serve only those who fit under an armed services program.

How much cost is involved for the applicants?

In the year 1981, in North Dakota, some 6204 marriages were performed[9] which means some 12,408 premarital syphilis serologies were done, and in 1982, through August, some 4246 marriages were performed[10] for a total of 8492 premarital syphilis serologies. During 1981, some 8561 syphilis serologies were performed at the Public Health Laboratory[11] at no cost to individuals which leaves some 3847 tests done at other laboratories. If the average cost of $5.95 from the survey is used for collecting the 8561 samples sent to the Public Health Lab, a cost of approximately $50,938 results, and if the average cost of $8.55 from the survey for drawing, testing, and the physician's signature is used for the remaining 3847 tests, some $32,892 results for a total of $83,830.

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[9] N.D. State Department of Health, Vital Records Division, Bismarck.

[10] N.D. State Department of Health, Vital Records Division, Bismarck.

[11] N.D. State Department of Health, Laboratory Services, Bismarck.

This same testing through August 1982, with the same survey, had some 5440 tests being performed at the Public Health Lab[12] for $32,368 at other laboratories for $26,095, and a total of $58,463. These totals, do not include costs such as driving to and from the clinic or doctor's office, nor does it include any physical check ups if required by physicians, and these costs are going up more and more every year.

The Public Health Laboratory costs also run high. The estimated cost per test from the Public Health Lab for premarital syphilis testing is $1.21.[13] This cost includes reagents, labor and overhead. At present, the Public Health Lab does not charge for premarital testing because it is mandated, and is a disease control program.

Premarital syphilis records, in the Health Department, go back to 1944. Since this time, up to October 1982, the Bismarck Public Health Laboratory did some 167,439 premarital tests. At todays cost this adds up to $202,601. Since 1944, syphilis was detected for the first time in only two cases in the 167,439 blood tests performed for a 38 year period. This is not to say that there were only two positive syphilis premarital tests, because there were actually a number of them. All but two were either previous treated syphilis cases, congenital syphilis cases, or administratively disposed of. The State also operated a Public Health Laboratory in Grand Forks for a number of years. This laboratory up until its closing did some 191,027 premarital syphilis serology tests. Records were unavailable for the number of syphilis cases detected for the first time from this

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[12] N.D. State Department of Health, Laboratory Services, Bismarck.

[13] N.D. State Department of Health, Laboratory Services, Bismarck.

laboratory's testing, however, the Director of Disease Control gives the two positives from the Bismarck laboratory as the total number of positive premarital syphilis cases detected for the first time from both labs. This brings the total number of premarital tests up to 358,466 with only two positives. This figures to $216,872 to find a single case. These costs do not reflect any blood drawing, lab testing, physician signatures on the certificates, or required check up costs, or even hidden expenses as discussed, but only testing expense by the Public Health Laboratory.

The Costs Of The Law: Who Bears The Cost

It can be seen that there are substantial costs for the following of the premarital mandate. But, when it comes down to the bottom line, that is, who bears the cost of this mandate, the public seems to be the one. They are the ones who have to pay for all the indirect costs as well as the direct costs, and they are even the ones who pay, through taxes, the Health Departments expenses for their part in this law. The marriage applicants are the public most hard hit by the costs.

The Laws Outcome: What Is The Laws Goal

As stated in the section entitled "North Dakota's Premarital Law: History Of It," the goal of the law is disease control. But, it can be seen that circumstances are quite different today than they were in 1939, when the mandate was first passed by the legislature. "Since the general sociologic expectations in the 1940's for young people were marriage and the early formation of a family, premarital laws mandating a serologic test for syphilis were also promulgated in most states to screen such persons and prevent congenital syphilis as well."[14] Syphilis control, and congential syphilis especially, are very much goals of modern day, and should be because of the possible human damage the disease can cause. In fact, federal programs and grants are set up for syphilis control other than premarital mandates.

The Laws Outcome: Has It Reached Its Goal

By putting a few facts together, it should be possible to see that the law has not reached its goal.

Looking back to "The Costs Of The Law: How Much Does It Cost Survey" it was found that only two cases of syphilis were diagnosed for the first time from premarital screening, while some 358,464 tests failed to do this. This law produces such a small fraction contribution to overall syphilis control. These two positive cases represent only 0.0006% when considering the total premarital testing since 1944, or 0.06% of the total syphilis cases since 1939.

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[14]Yehudi M. Felman, MD, "Laws Mandating Premarital Serologic Tests for Syphilis Should be Repealed, Archives of Dermatology, Vol. 118, March 1982, p. 145.

Screening tests are of little value in controlling syphilis unless they lead to the discovery of new cases.[15] How can something reach a goal when it produces no results? And, this is the case with North Dakota's premarital law.

This premarital syphilis screening may not go after the right population as the following indicates.

> "While it is true that there have been huge increases in sexually transmitted diseases such as nongonococcal urethritis, gonorrhea, and genital herpes simplex infections, as well as their complications that affect pregnant women and neonates, the incidence of infectious syphilis had dropped dramatically in the heterosexual population. While syphilis today has not been eradicated, the only population in which it remains endemic is the male (and not the female) homosexual population. From this population, which makes up the largest percentage of national syphilis cases, premarital syphilis screening is of no value."[16]

Premarital syphilis testing for congenital syphilis is likewise of no value in births involving unwed mothers, or unmarried couples living together.

> "The members of the 'baby boom' population that are now adults of child-bearing age do not necessarily subscribe to the same family goals of their parents. For one thing, they do not necessarily opt for a child in the first year of marriage as many of their parents did. Instead, they tend to plan their families after a measure of economic stability is achieved, thus almost completely eliminating the potential value of the premarital mandate in preventing congenital syphilis in their first born."[17]

North Dakota has over the years cut its syphilis rate quite dramatically as can be seen by the following table.

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[15] Yehudi M. Felman, MD, "Should Premarital Syphilis Serologies Continue To Be Mandated by Law?" JAMA, Vol. 240, No. 5, Aug. 4, 1978, p. 459.

[16] Yehudi M. Felman, MD, "Laws Mandating Premarital Serologic Tests For Syphilis Should Be Repealed," Archives of Dermatology, Vol. 118, March 1982, p. 145.

[17] Ibid. p. 146.

North Dakota Syphilis Case Rate[18]

YEAR	SYPHILIS #CASES	SYPHILIS RATE*	YEAR	SYPHILIS #CASES	SYPHILIS RATE*	YEAR	SYPHILIS #CASES	SYPHILIS RATE*
1925	230	34.64	1944	226	43.21	1963	47	7.43
1926	238	35.61	1945	197	37.73	1964	30	4.74
1927	189	28.14	1946	271	50.09	1965	19	3.00
1928	316	46.87	1947	318	57.50	1966	27	4.26
1929	516	76.09	1948	307	54.62	1967	34	5.37
1930	409	60.14	1949	237	40.65	1968	41	6.48
1931	413	61.19	1950	250	40.58	1969	54	8.53
1932	440	65.94	1951	183	29.95	1970	34	5.50
1933	290	43.76	1952	115	18.60	1971	23	3.72
1934	303	45.90	1953	79	12.64	1972	22	3.52
1935	222	33.77	1954	56	8.87	1973	14	2.18
1936	206	31.61	1955	58	9.07	1974	28	4.36
1937	430	66.73	1956	58	9.04	1975	35	5.45
1938	423	66.08	1957	24	3.72	1976	36	5.58
1939	367	57.30	1958	41	6.42	1977	15	2.31
1940	369	57.92	1959	49	7.63	1978	26	3.99
1941	368	59.74	1960	57	9.01	1979	6	0.92
1942	349	59.45	1961	36	5.69	1980	13	1.99
1943	318	57.81	1962	37	5.85	1981	19	2.90

*Per 100,000 population.

From the table, it can be seen that there has been a number of syphilis cases in North Dakota over the years. With only two of these cases directly attributed to the premarital mandate since 1944, the table shows that mandate has had very little effect on the total of syphilis cases found in North Dakota. This suggests that people are seeking medical attention resulting in the detection of syphilis without a mandate forcing this upon them.

In North Dakota to say that all premarital applicants should be tested for syphilis since a negative test result would assure health officials that such persons do not have the infection is of no value. It serves no purpose because syphilis control is to detect disease, not to prove it is not there.

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[18]N.D. State Department of Health, Disease Control Division, Bismarck.

The General Evaluation Criteria: Benefit Cost, Cost Effectiveness, And Comparison Evaluation

The title of this section may be somewhat misleading because benefit-cost analysis, cost effectiveness and comparison evaluation are actually methods for evaluation and not criteria. What this title means, and actually what this section will do, is to have a short discussion of each of the evaluation methods, and then apply the methods to find which method or methods are most applicable to evaluation of the premarital law requiring syphilis serologies in North Dakota form the information attained thus far in this study.

Benefit-cost analysis concentrates on assessing programs and determining those components or areas that best achieve the goals. Benefit-cost analysis has been also applied to calculate the returns on investments in programs.

> "In essence, the cost-benefit analyst attempts to identify the benefits of a program, both tangible and intangible; he looks at the cost of conducting the program, the direct and indirect; then he tries to put them into a common unit of measure-dollars. The ratio of benefits to costs is an indication of the return that society is getting from its investment in the program."[19]

> "Identifying all favorable and unfavorable impacts of a project and giving them a dollar value is a difficult task. Many consequences are unanticipated and thus omitted from the analysis. In the fact of uncertainty, bad assumptions about possible costs and benefits may be made... Direct benefits and costs are closely related to the objective (or intent) of the project; indirect benefits and costs are by-products... Benefits and costs that can be evluated in the market are called tangible, and others that cannot are

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[19]Carol H. Weiss, Evaluation Research, (New Jersey: Prentice-Hall, Inc., 1972), p. 85.

> termed intangible... Without a market test for value, intangible benefits and costs cannot be valued in dollars with a high degree of certainty and thus are estimated. Again, the danger exists that intangible benefits will be overestimated and intangible cost ignored or underestimated, miscalculations that will change the results of the analysis."[20]

To apply benefit-cost analysis to this study of North Dakota's premarital syphilis mandate would be possible, however with considerable difficulty. The main difficulty being benefit measurement. The cost could be calculated as it was in "The Costs Of The Law: How Much Does It Cost Survey" to get the total amount spent thus far by the Health Department, and the cost per positive of previously undiagnosed cases of syphilis. How could the benefits of finding these two cases be calculated? Would the estimates for any possible effects the disease could bring on have to be estimated? What about congenital syphilis and its effects? The benefits are too unpredictable and intangible.

Comparison evaluation as used in this study means a time comparison of the premarital law under study. A comparison to answer the questions of what would have happened if the program had not been implemented? And, how does this assessment compare with what actually happened? The difficult part of comparison evaluation is to determine what would have happened without the program so that it's possible to tell if changes associated with the program came from the program itself or from other factors that that would have been present anyway.[21]

When looking at what would have happened without the mandate, it

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[20]Robert D. Pursley and Neil Snortland, Managing Government Organizations (Massachusetts: Duxbury Press, 1980), p. 390.

[21]Ibid.p. 424.

can be seen that two cases of previously undiagnosed syphilis are attributed to the program. What would have happened if the program had not been put into effect? The two cases would have been missed, but what would have resulted from this? This is difficult to assess and turns out to be a guessing game, the same as in benefit measurement in benefit-cost analysis.

Cost effectiveness may be the method best suited for this study. The data which this study has brought out thus far would seem to fit rather well into this type of evaluation method, the data on costs and outcomes that is.

> "The difficulties of measuring benefits and costs in dollars has led to another method of efficiency planning known as cost effectiveness analysis. Cost effectiveness analysis is used when benefits and costs are hard to compare directly, and when the total cost (budget) for a purpose is fixed and alternative projects are evaluated to see which is the most effective in achieving the purpose. Benefits are not measured in dollars, and no attempt is made to determine the net benefit. Cost effectiveness analysis can be used to select the project that produces the maximum effectiveness that can be achieved for each level of expenditure for a specific purpose."[22]

Since benefits are hard to measure under the premarital law concerning syphilis, cost effectiveness should work well.

> "For a screening program to be considered cost-effective, the disease screened should be of serious or catastrophic consequence and easily preventable or treatable, and the cost of the screening test itself should be negilgible.... The results from syphilis screening in general are of little consequence in syphilis control.... Positive screening tests are of little value in controlling syphilis unless they lead to the discovery and treatment of actual disease."[23]

From "Syphilis And History", and "Syphilis The Disease" it can be

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[22]Robert D. Pursley and Neil Snortland, Managing Government Organizations, (Massachusetts: Duxbury Press, 1980), p. 392.

[23]Yehudi M. Felman, MD, "Should Premarital Syphilis Serologies Continue To Be Mandated by Law?" JAMA, Vo. 240, No. 5, Aug. 4, 1978, p. 459.

seen that the disease has very serious consequences and is easily treatable.

Syphilis screening at the Public Health Laboratory costs an estimated $1.21 per test, but this does not represent those hidden costs. Of all the positive screening tests for syphilis, only two represented new cases. It cost approximately $216,872 to detect each of these new cases. This is not negilgible.

Premarital screening is not the most effective method because it does not produce the maximum effectiveness, but rather a very small amount of effectiveness at such a large cost. It is not the best alternative. The following table represents effectiveness of the premarital mandated testing.

Effectiveness Of Mandated Serologies in ND*

Reactive from all sources (1944-1981)	1351
Reactive from mandated testing (1944-1981)	2
Percent of mandated reactive tests to reactive from all sources	0.15%
Percent of reactives for mandated tests performed	0.0006%

*Statistics come from my computations based on my totals from counting premarital tests from Health Department records.

The effectiveness percentages from this table actually represent the ineffectiveness of the law because of their minuteness.

CHAPTER THREE

SUMMARY AND CONCLUSION

Evaluation Criteria Summary

In going back and looking through what was brought out in Chapter Two, it can be seen that much of the data points in the same direction.

Syphilis is a communicable disease that has been around for a long time and can cause a variety of damaging effects. Because of its communicable properities and effects, syphilis screening programs have been set up to control the disease, and especially its congenital consequences. The premarital mandate requiring syphilis serology testing is one such screening program. It was established in 1939, when sociological expectations for early family formation existed, and treatment was not effective. Circumstances have changed since this time. Family expectations are different, syphilis is very effectively treated, and is likewise congenital infection. This mandate requires the applicants for marriage in the state to be tested for syphilis, as well as requiring the Health Department to monitor, approve, test, train and consult other laboratoriies in the state for this testing. This mandates carries a price tag that society must bear. The cost to find a single positive at the State Public Health Laboratory is $216,872 and rising, and this does not include other incurred expenses by the applicants. In 39 years, the laws outcome is questionable, for it has produced only two previously undiagnosed cases of syphilis. It has very little effect on total syphilis diagnosis.

At the present, 19 states have no provisons for premarital syphilis serology testing. The Center for Disease Control does not say to keep or repeal premarital mandates but to weigh all possibilities and consider local situations. The North Dakota officials directly in contact with the law favor its repeal for productivity and cost reasons, and the literature available points toward abolition. The evaluation method of cost effectiveness lends itself to this study better than benefit-cost analysis or comparison evaluation, and shows cost ineffectiveness.

The indicators of: requirements, costs, outcomes or goal attainment, cost-effectiveness, low productivity and changing circumstances point to the answer. They point to unjustitiable. They support the null hypothesis. This law should be abolished.

> "There is no question that, if possible, every single case of syphilis should be found and treated; but when the cost of doing this becomes prohibitive, as we believe to be the case with mandated premarital tests for syphilis, other means must and can be found to accomplish these tasks. We have previously suggested, as one option to be evaluated, the screening of pregnant women in the first trimester."[24]

Something Else Instead: Another Law

Does the repeal of this premarital mandate mean that something else such as another law will be required to control congenital syphilis instead. In this case it does not because North Dakota already has a law requiring syphilis testing in pregnancy. What is needed is flexibility.

> "But who is better to decide on these various factors, which change from time to time, than the public health authority in each state? A legislative law once promulgated regardless of how well conceived originally, is not easily changed to meet

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[24]Yehudi M. Felman, MD, "Repeal of Mandated Premarital Tests for Syphilis: A Survey of State Health Officers", American Journal of Public Health, Vol. 71, No. 2, Feb. 1981, p. 159.

changing conditions. Public health officials should have the authority to establish premarital screening by administrative decision."[25]

Screening women at the time of marriage is questionable since syphilis serologies are required by North Dakota law for prenatal studies. "Screening of pregnant women for syphilis protects both the mother and the fetus and has almost completely eliminated congenital syphilis formerly one of the most feared complications of this disease."[26]

The Significance Of The Study: What's The Significance

This study is significant because it has proved a law unjustifiable and yet it survives on the books. The law has been bureaucratically administered by the Health Department since its institution by the legislature who have failed to remove it despite its inadequacies causing the public costs for following the mandate to ever increase. How could this law remain for so long, survive through all the unjustifiability? Was this law not properly evaluated? If at all?

The Significance Of The Study: What Are The Governmental Alternatives For Evaluation Processes

Who knows how many laws have outlived their usefulness and have become unjustifiable? Numerous sources recommend evaluation, and it should be done. But, how can evaluations be carried out or even guaranteed? Each law is different, and so many circumstances revolve around it that only general evaluation standards can be utilized. Some possible paths

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[25]Yehudi M. Felman, MD, "Repeal of Mandated Premarital Tests for Syphilis: A Survey of State Health Officers", American Journal of Public Health, Vol. 71, No. 2, Feb. 1981, p. 159.

[26]Yehudi M. Felman, MD, "Should Premarital Syphilis Serologies Continue To Be Mandated by Law?", JAMA, Vol. 240, No. 5, Aug. 4, 1978, p. 460.

October 8, 1982

Venereal Disease Research Branch:

I am beginning to study the area of premarital laws which require certain clinical testing of individuals desiring to get married. It seems that some states have moved to abolish these mandates. North Dakota at present has a syphilis serology premarital mandate which is in question. What arguments for or against the abolition of this law do you take a stand with? Why is this stand taken? And, what alternatives to replace these mandates, if any, do you see as these laws are repealed?

Your prompt reply will be greatly appreciated.

Sincerely,

Roger M. Kramer, Assistant Director
Microbiology and Immunology
Laboratory Services Section
ND State Dept. of Health
Box 1618
Bismarck ND 58505

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

October 21, 1982

Roger M. Kramer, Assistant Director
Microbiology and Immunology
Laboratory Services Section
ND State Department of Health
Box 1618
Bismarck, North Dakota 58505

Dear Dr. Kramer:

Enclosed is a review of the subject of premarital screening for syphilis. Alternatives to consider depend upon the setting and might include improved antenatal screening where congenital syphilis is a problem or more intensive contact tracing when cases are discovered.

Sincerely yours,

Stuart T. Brown

Stuart T. Brown, M.D.
Coordinator for International
VD Control Activities
Venereal Disease Control Division
Center for Prevention Services

Enclosure

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Premarital Syphilis Screening: Weighing the Benefits

ROBERT J. KINGON, MPA, AND PAUL J. WIESNER, MD

As reported by Felman in this issue of the Journal,[1] many State health authorities are now deliberating the question of whether to retain, repeal, or otherwise modify requirements for mandatory premarital syphilis screening. Maine was the first state to repeal its premarital law in 1972.[2] In 1978 an analysis by Felman argued for the abolition of these laws nationwide.[3] Rothenberg, *et al.*, described various epidemiologic factors which should be addressed in considering repeal of premarital laws.[4] The decision to modify or repeal these laws is not a simple one.

Most proponents of repeal have cited the lack of cost effectiveness of premarital screening. To use the term "cost effectiveness" implies an ability to redirect existing resources from premarital screening to other syphilis control activities considered more effective in discovering early cases. With premarital syphilis screening, program officials do not have that flexibility because most of the screening is performed in the private sector. In most states only a relatively small proportion of the total resources supporting premarital screening fall within the influence of program management, i.e., the processing of tests in public laboratories and the follow-up of reactive tests by program staff.

The measure of effectiveness most often used by proponents of repeal has been the number of untreated persons who are detected in the primary, secondary, or early latent (under one year's duration) stage of disease. This sole focus on yield of new early cases neglects other potential benefits.

To make an informed decision on retaining or repealing premarital syphilis screening, the state policymaker must estimate the value of all the potential benefits derived from the activity and weigh them against total costs. A listing of benefits (in descending order of importance) which should be considered include:

1. Detection and prevention of early syphilis.
2. Detection of latent disease and prevention of complications.
3. Surveillance information for program management.
4. Prevention of congenital syphilis.
5. Provision of other preventive services through premarital examination.
6. Provision of quality control in laboratory performance.

Detection and Prevention of Early Syphilis: The number of persons detected with untreated early syphilis through premarital syphilis screening is accurately described by Felman in this issue of the Journal.[1] State health officials should also assess the degree to which these patients serve as index cases in discovering additional early cases, preventing further disease transmissions, and containing potential disease outbreaks. These benefits in detecting index cases may be valued differently by states, depending upon the prevalence of early syphilis and distribution of disease within the state.

Detection of Latent Disease and Prevention of Complications: The first premarital screening law, enacted by Connecticut in 1935, was cited as a model in the design of the "Wasserman dragnet." As described by Parran, the "Wasserman dragnet" was one component of a national strategy to control and eliminate syphilis.[5] While the other major components—education and improved treatment facilities (stressing free and accessible services)—were designed to promote the discovery of infectious syphilis, the "Wasserman dragnet" was designed to discover latent syphilis. Since Parran recognized that education and treatment services could only result in the identification of a portion of the new infections, additional means for detecting untreated latent disease were required. In 1973, Henderson reemphasized this purpose of serologic screening in a discussion of routine serologic testing for syphilis among hospital inpatients.[6]

The annual number of serologic tests for syphilis performed at the time of Parran's proposal totaled approximately two million.[5] In 1978, over 45 million serologic tests were performed in this country.[7] While a small proportion of these tests are performed because of suspicion of syphilis, most are conducted routinely for the purpose of discovering latent disease. During 1978, 1,134,891 reactive serologic tests for syphilis were reported to state health departments. Of the 155,340 persons with reactive tests who were not known to be treated and required follow-up by health departments, 49,987 (nearly one-third) were identified as new cases. Of these, 11,495 were diagnosed as infected in the primary or secondary stages and 37,592 in latent and late stages.[8]

There are no national data on the number of persons with latent syphilis (over one year's duration) who were detected specifically through premarital screening. States can obtain this information from their records of dispositions from the follow-up of persons with reactive serologic tests. Although the yield of latent cases from screening activity now is much less than the yield in 1946, Dr. Parran's concern for identifying infections missed by other means is as true today as in the 1930s. Without serologic screening to detect latent cases, the number of late active cases would likely increase. While this argument tends to gain most support in the screening of older persons in settings such as hospitals, it should be noted that the median age for marriage in 1977 was 24.0 for men and 21.6 for women;[9] more than one-half of those being married were in or beyond the 20–24 age group.

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Editor's Note: See also related article, p. 155, this issue.

That age group has the highest reported rate of infectious syphilis (30.4 cases per 100,000 population in 1977).[10] In addition, of the 5,405 admissions to resident mental institutions during the period 1969–75 with a diagnosis of organic brain syndrome caused by syphilis, 598 were in the age group 20–34.[11]

Surveillance Information for Program Management: The four million premarital serologic tests now performed annually account for less than 10 per cent of total serologic tests performed. Yet premarital testing is the only widespread population-based syphilis screening activity which surveys both sexes. As such, reactivity rates by stage of disease detected can be calculated to measure trends and disease distribution over time among newly marrieds. The utility of this approach is most beneficial in those communities with a sufficient number of cases detected to allow analyses of population subgroups.

Prevention of Congenital Syphilis: The benefit in preventing congenital syphilis through premarital testing is difficult to assess. Prenatal testing is a better means of detecting syphilis among pregnant women, yet some women detected with syphilis through premarital screening may not seek prenatal care and be tested. Because it is important to detect syphilis early in pregnancy, the number of women who are pregnant at the time of marriage should also be considered. Currently, four states which have premarital laws do not have legislation which mandates prenatal serologic testing.[12] These states should carefully weigh this potential benefit of premarital screening in light of changing disease prevalence in communities.

Provision of Other Prevention Services: In addition to requirements for a serologic test for syphilis, some states require premarital examinations for other diseases:

- sixteen states require a certification that the individuals are free of gonorrhea,
- five states require rubella testing among females,
- one state requires a test for tuberculosis, and
- one state requires testing for sickle cell anemia.[12]

Interestingly, Colorado, which discontinued premarital tests for syphilis in July 1979, retained rubella-antibody screening programs among women under the age of 45. A cost-benefit study of mandatory premarital rubella-antibody screening programs suggested that only in Colorado was the testing potentially cost beneficial.[13] However, cost calculations in this study excluded visits to providers since the program was originally "piggy backed" on syphilis premarital testing. States must examine the range of services being provided under the umbrella of premarital screening and apportion the costs involved to each of the services being provided.

One state health department recently surveyed practicing physicians regarding premarital examinations. A majority of the responses disagreed with the existing law primarily because of the syphilis serology requirement and the lack of clear parameters defining the physical examination. However, a similar majority believed that there was a need for a premarital examination. Of those favoring a premarital examination requirement, the most frequently mentioned services to be provided were a pelvic/genital examination and counseling. The surveyed physicians clearly felt that premarital visits to a health care provider have value beyond screening for specific diseases. Health programs should entertain the potential which exists for delivering other important preventive services such as counseling regarding genetic factors, family planning, and general lifestyle adjustments. If premarital examinations are to continue for other reasons, the total cost of syphilis serologic testing within a state must be recalculated in arriving at a policy decision.

Provision of Quality Control in Laboratory Performance: Another potential benefit of premarital serologic screening is related to laboratory performance. Nearly all premarital laws specify that only approved laboratories can provide the serologic test and must undergo onsite reviews and/or be enrolled in a proficiency testing program. If premarital laws were repealed, some quality assurance might be lost. At a minimum, states which repeal the premarital law must plan for maintaining quality control by alternative measures.

In conclusion, the overall value of the *routine* use of serologic tests in the control of syphilis and reduction of complications has been clearly documented during the past four decades. This value in outpatient settings has recently been underscored by Chapel in an analysis of patients with secondary syphilis who were seen by physicians in community practice. His analysis found that one-third of these patients were diagnosed *only* on the basis of a routine serologic test.[14] The specific contribution of premarital testing to the overall value of routine serologic testing is less certain and must be decided in each state.

Decisions regarding premarital serologic tests must be made by responsible officials in light of epidemiologic factors in the community being served. Felman portrays the dilemma which state health officials must face in deciding the appropriateness of mandated premarital syphilis serologic testing. Our hope is that the full range of benefits which may be derived from premarital examinations will be rigorously investigated by policymakers within each affected jurisdiction. We do not oppose a state's decision to repeal its premarital laws. We do oppose an over-simplified cost-effectiveness analysis leading to that decision.

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October 8, 1982

I am doing a graduate school survey on North Dakota's premarital law which requires all individuals who desire to marry in this state to have a syphilis serology test performed on them.

The following survey contains only a few short self explanatory questions. I ask that you answer these promptly and return the completed questionnaire in the provided envelope.

Please read through <u>all</u> questions carefully before providing the answers. If a question does not relate to your laboratory or institution, place an "X" in the answer section.

What is the dollar amount charged by your institute:

-to only draw the blood sample for the premarital syphilis serology test (this does not include the cost for the test) $_____

-to only test a premarital blood sample for syphilis (this may pertain if other physicians, clinics, etc., send blood specimens to your institute for premarital testing) $_____

-to both draw the blood sample and test it for syphilis at your institution $_____

-to only have the physician sign the premarital form (this does not include the cost of drawing or testing the blood sample for syphilis) $_____
(Note: this may be an estimate if the amount varies from physician to physician.)

-to have the blood drawn, tested, and the premarital form signed by a physician at your institute $_____

Thank you for your cooperation.

Sincerely,

Roger M. Kramer

NORTH DAKOTA STATE DEPARTMENT OF HEALTH

DIVISION OF LABORATORIES

Rules and Regulations For Approval to Perform Premarital & Prenatal Tests for Syphilis

REGULATIONS 14-03

TABLE OF CONTENTS

GOVERNOR

HONORABLE WILLIAM L. GUY

STATE HEALTH COUNCIL

Sister Mary Adrian Fisch, Chairman, State Hospital Association, Fargo, North Dakota

Miss Margaret F. Heyse, Vice Chairman, State Nurses Association, Grand Forks, North Dakota

Mr. Al. Doerr, Secretary, State Pharmaceutical Association, Bismarck, North Dakota

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J. D. Ott, D.D.S., State Dental Association, Dickinson, North Dakota

Mrs. Anna Powers, Lay Member, Leonard, North Dakota

William T. Powers, M. D., State Medical Association, Grand Forks, North Dakota

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James R. Amos, M. D.
State Health Officer

State of North Dakota
State Health Council
to
Perform Premarital and Prenatal
Tests for Syphilis

Pursuant to the authority vested in the State Health Council of the State of North Dakota, the said Council has promulgated and by these presents, hereby publishes, Rules and Regulations of the State Health Council of the State of North Dakota, as authorized by the Laws of the State of North Dakota.

These Rules and Regulations were adopted by the State Health Council of the State of North Dakota, the 31st day of August, 1971, at Bismarck, North Dakota, and became effective from the date of adoption.

NORTH DAKOTA STATE HEALTH COUNCIL

by James R. Amos
State Health Officer

Date Adopted: August 31, 1971

Legal Basis for Adoption of Rules and Regulations
to Perform Premarital and Prenatal
Tests for Syphilis

(Source: Title 14 North Dakota Century Code)

Title 14 MARRIAGE CONTRACT Chapter 14-03

Section
14-03-13 (as amended). "STANDARD SEROLOGICAL TEST" DEFINED.) A standard serological test shall be a laboratory test for syphilis approved by the state health officer and shall be performed by the state department of health, or by any other laboratory approved by the state health officer. The county judge shall collect a fee of not to exceed fifty cents for each serological test performed in this state, which shall be paid by him into the state treasury on the first day of July. The fee shall be collected from each applicant for a marriage license upon whom the test has been performed. State public health laboratories outside of the state of North Dakota which have been approved by the state health officer shall make their own arrangements as to the amount and manner of collecting their fees for the service.

DEFINITIONS

ADVISORY COMMITTEE -- A group of consultants appointed by the State Health Officer to advise the Department on matters relating to these regulations.

DEPARTMENT -- Shall mean the North Dakota State Department of Health.

DIVISION OF LABORATORIES -- A Division of the North Dakota State Department of Health.

LABORATORY -- Any place in which a serologic test for syphilis is performed.

SEROLOGIST -- Any person conducting a serologic test for syphilis.

OPINION

STATE OF NORTH DAKOTA

HELGI JOHANNESON

ATTORNEY GENERAL

BISMARCK, NORTH DAKOTA 58501

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CLERK
JOHN R. ERICKSON
AUDITOR

July 22, 1971

James R. Amos, M. D.
State Health Officer
North Dakota State Department
of Health
State Capitol
Bismarck, North Dakota

Dear Doctor Amos:

We have this date examined propsed State Health Council Regulations 14-03-01 through 14-03-09, relating to Approval to Perform Premarital and Prenatal Tests for Syphilis considered by the State Health Council at their meeting on June 22, 1971.

From such examination it is our opinion that such regulations when duly promulgated and filed as otherwise provided by law, will be legal, valid and binding rules of the North Dakota State Health Council having the force and effect of law.

Yours very truly,

Helgi Johanneson

Helgi Johanneson
Attorney General

HJ:a

RULES AND REGULATIONS

R 14-03-01 AUTHORIZATION AND ADMINISTRATION

A. Responsibilities - North Dakota State Department of Health

It shall be the responsibility of the Department to establish rules and regulations for the performance of premarital and prenatal serologic tests for syphilis in any laboratory in the State and to require any laboratory performing such a test to conform to these standards. It shall be the policy of the Department to assist any laboratory in the State which desires to obtain approval to conduct serologic tests for syphilis to gain and maintain such approval. The Department shall offer training, laboratory reviews and consultation to any laboratory requesting such services.

B. Requirements for Approval

Any laboratory desiring to be approved to perform premarital and prenatal syphilis serologic tests must have official approval of the North Dakota State Department of Health. Approval is conditional on meeting certain minimum standards for personnel and facilities, as well as minimum technical standards for procedures used to examine specimens submitted to the laboratory for syphilis serology. Such standards are defined in Section R 14-03-08, below.

In addition, the laboratory shall have:

1. Successfully participated in an intra-state syphilis serology proficiency testing program in which the serologist desiring approval has:
   a. Examined and reported the results on all of not less than sixty (60) specimens submitted to the participating laboratory. Not less than fifty percent (50%) of these specimens shall be in duplicate.
   b. Demonstrated a test reproducibility within acceptable limits which will be set at the beginning of each year.
   c. Demonstrated acceptable agreement with test results of reference laboratories on individual serums. Acceptable limits of performance will be set at the beginning of each year.
2. Agreed to an on-site visit by a representative of the Division of Laboratories at various times for survey of equipment and procedures.
3. Show that a minimum volume of 50 serology specimens per month will be performed.
4. Agree to perform a quantitative test on all reactive and weakly reactive test results. In addition, agree to submit all reactive and weakly reactive serums to the Public Health Laboratory for a confirmatory test procedure.

R 14-03-02 Failure to Meet the Minimum Requirements

Failure to meet the minimum requirements, as determined by on-site survey and performance evaluation shall be sufficient grounds to deny approval until such time as the minimum standards are met.

Tests employed must be one listed in the most recent publication or amendment of "Manual of Tests for Syphilis" U. S. Department of Health, Education & Welfare, Public Health Service, Publication No. 411. Tests are to be performed and reported in accordance with the standard procedures given in this manual.

R 14-03-03 Initial Approval - Provisional Approval

A laboratory wishing to be considered for approval must submit a written request for a survey on a form to be obtained from the Division of Laboratories, North Dakota State Department of Health, and returned to the Director, Division of Laboratories, North Dakota State Department of Health, Box 1618, Bismarck, North Dakota. The request for survey must indicate the test(s) for which approval is desired. The purpose of this review will be to determine whether the laboratory and affected personnel meet the minimum established standards as set forth in R 14-03-08.

Before provisional approval is granted twenty (20) reference specimens must have been examined using the test indicated in the application for approval. Observations by the surveyor and the results reported on the twenty (20) reference tests shall be submitted to an advisory committee designated by the State Health Officer to evaluate the report and recommend action to be taken. Provisional approval may be granted for ninety (90) days if the standards are met.

R 14-03-04 Full Approval

A provisionally approved laboratory must examine and report satisfactorily results on an additional forty (40) reference specimens within sixty (60) days from the date of provisional approval. If this requirement is met, full approval will be granted. Full Approval shall remain in effect during the calendar year providing the laboratory continues to meet the requirements listed in R 14-03-01 B above.

The approved laboratory shall notify the Health Officer in writing when changes in affected personnel occur.

R 14-03-05 Renewal of Approval - Maintenance Status

A laboratory wishing to maintain approval status must continue to meet the requirements for approval as specified in these rules and regulations.

A laboratory meeting the requirements of these regulations will be issued a certificate or letter of approval for the calendar year in which renewal is requested.

R 14-03-06 Publishing Lists of Approved Laboratories

The North Dakota State Department of Health shall publish annually a list of laboratories meeting the minimum standards established under these rules and regulations. Included will be the name and location of the laboratory and the serologist(s) qualified to perform the tests approved. This list shall be sent to all hospital laboratories and each county judge's office in the State. The list will indicate provisional or full approval. Amendments to the list will be made as they occur.

R 14-03-07 Laboratories Approved to Conduct Premarital and Prenatal Tests for Syphilis

Intra-state laboratories approved by the methods in these rules and regulations, the offical laboratory of

any state public health agency and the branches of these laboratories, laboratories approved by these state agencies, laboratories of the Armed Forces of the United States and the United States Public Health Service will be accepted under the premarital-prenatal laws of this State.

R 14-03-08 MINIMUM STANDARDS TO BE EMPLOYED

The following minimum standards shall serve as the basis for approval of a laboratory to conduct premarital and prenatal tests for syphilis.

A. Personnel Qualifications

Minimum educational requirements for any person performing a serologic test for syphilis shall be the successful completion of a full course of study which meets all academic requirements for a bachelor's degree in medical technology or one of the biological sciences.

In addition to the baccalaureate degree, or equivalent, the serologist shall have demonstrated proficiency in syphilis serology as gained by attendance at pertinent courses or the equivalent in practical laboratory training and experience as determined by the State Health Officer.

A person who has been working in a clinical or public health laboratory for not less than five (5) years

at the time of the adoption of these standards, but who does not meet the above requirements, may also be qualified providing that, as determined by an advisory committee, such person has completed not less than one year of pertinent education beyond the high school level, or has received training through an acceptable training program, providing such a person is shown to be competent to perform these examinations as demonstrated by satisfactory participation in a proficiency testing program offered or authorized by the Division of Laboratories.

B. Quality Control

There is a quality control program in effect including the use of reference or control serum. Records of the use of such controls must be available.

C. Laboratory Equipment and Supplies

Space, facilities and equipment are of such a type to perform the serologic tests for syphilis.

The laboratory shall have on hand supplies and equipment prescribed by the author of the serologic test employed, as designated in the most recent publication or amendment of the "Manual of Tests for Syphilis", United States Department of Health, Education & Welfare, Public Health Service Publication No. 411.

R 14-03-09 Appeal

An applicant may petition the State Health Council for an administrative hearing and an appeal may be taken to the district court from any order or determination of the State Health Officer or Health Council. Any such appeal shall be taken in the manner provided in Chapter 28-32, "Administrative Agencies Practice Act" of the North Dakota Century Code.

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