

REPORT ON CHARGE I

April 24, 1973

Tuskegee Syphilis Study Ad Hoc
Advisory Panel

Acknowledgements

Subcommittee for Charge I

The Co-Chairmen wish to acknowledge the input of members of the subcommittee and panel members whose input and deliberations were essential to the final report for Charge I:

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FINAL REPORT

TUSKEGEE SYPHILIS STUDY AD HOC ADVISORY PANEL

REPORT ON CHARGE I-A

Statement of Charge I-A: Determine whether the study was justified in 1932.

Background Data

The Tuskegee Study was one of several investigations that were taking place in the 1930's with the ultimate objective of venereal disease control in the United States. Beginning in 1926, the United States Public Health Service, with the cooperation of other organizations, actively engaged in venereal disease control work.¹ In 1929, the United States Public Health Service entered into a cooperative demonstration study with the Julius Rosenwald Fund and state and local departments of health in the control of venereal disease in six southern states²: Mississippi (Bolivar County); Tennessee (Tipton County); Georgia (Glynn County); Alabama (Macon County); North Carolina (Pitt County); Virginia (Albermarle County). These syphilis control demonstrations took place from 1930-1932 and disclosed a high prevalence of syphilis (35%) in the Macon County survey. Macon County was 82.4% Negro. The cultural status of this Negro population was low and the illiteracy rate was high.

During the years 1928-1942 the Cooperative Clinical Studies in the Treatment of Syphilis³ were taking place in the syphilis clinics of Western Reserve University, Johns Hopkins University, Mayo Clinic, University of Pennsylvania, and the University of Michigan. The Division of Venereal Disease, USPHS provided statistical support, and financial support was provided by the USPHS and a grant from the Milbank Memorial Fund. These studies included a focus on effects of treatment in latent syphilis which had not been clinically documented before 1932. A report issued in 1932 indicated a satisfactory clinical outcome in 35% of untreated latent syphilitics.

The findings of Bruusgaard of Oslo on the results of untreated syphilis became available in 1929.⁴ The Oslo study was a classic retrospective study involving the analysis of 473 patients at three to forty years after infection. For the first time, as a result of the Oslo study, clinical data were available to suggest the probability of spontaneous cure, continued latency, or serious or fatal outcome. Of the 473 patients included in the Oslo study, 309 were living and examined and 164 were deceased. Among the 473 patients, 27.7 percent were clinically free from symptoms and Wassermann negative;

14.8 percent had no clinical symptoms with Wassermann positive; 14.1 percent had heart and vessel disease; 2.76 percent had general paresis and 1.27 percent had tabes dorsalis. Thus in 1932, as the Public Health Service put forth a major effort toward control and treatment, much was still unknown regarding the latent stages of the disease especially pertaining to its natural course and the epidemiology of late and latent syphilis.

Facts and Documentation Pertaining to Charge I-A

1. There is no protocol which documents the original intent of the study. None of the literature searches or interviews with participants in the study gave any evidence that a written protocol ever existed for this study. The theories postulated from time to time include the following purposes either by direct statement or implication:⁵⁻⁷

- a. Study of the natural history of the disease.
- b. Study of the course of treated and untreated syphilis (Annual Report of the Surgeon General of the Public Health Service of the United States 1935-36).
- c. Study of the differences in histological and clinical course of the disease in black versus white subjects.
- d. Study with an "acceptance" of the postulate that there was a benign course of the disease in later stages vis-a-vis the dangers of available therapy.
- e. Short term study (6 months or longer) of the incidence and clinical course of late latent syphilis in the Negro male (From letter of correspondence from T. Clark, Assistant Surgeon General, to M.M. Davis of the Rosenwald Fund, October 29, 1932) — Original plan of procedure is stated herein.
- f. A study which would provide valuable data for a syphilis control program for a rural impoverished community.

In the absence of an original protocol, it can only be assumed that between 1932 and 1936 (when the first report⁵ of the study was made) the decision was made to continue the study as a long-term study. The Annual Report of the Surgeon General for 1935-36 included the statement: "Plans for the continuation of this study are underway. During the last 12 months, success has been obtained in gaining permission for the performance of autopsies on 11/15 individuals who died."

2. There is no evidence that informed consent was gained from the human participants in this study. Such consent would and should have included knowledge of the risk of human life for the involved parties and

information re possible infections of innocent, non-participating parties such as friends and relatives. Reports such as "Only individuals giving a history of infection who submitted voluntarily to examination were included in the 399 cases" are the only ones that are documentable.⁵ Submitting voluntarily is not informed consent.

3. In 1932, there was a known risk to human life and transmission of the disease in latent and late syphilis* was believed to be possible. Moore³ 1932 reported satisfactory clinical outcome in 85% of patients with latent syphilis that were treated in contrast to 35% if no treatment is given.

4. The study as announced and continually described as involving "untreated" male Negro subjects was not a study of "untreated" subjects. Caldwell⁸ in 1971 reported that: All but one of the originally untreated syphilitics seen in 1968-1970 have received therapy, although heavy metals and/or antibiotics were given for a variety of reasons by many non-study physicians and not necessarily in doses considered curative for syphilis. Heller⁶ in 1946 reported "about one-fourth of the syphilitic individuals received treatment for their infection. Most of these, however, received no more than 1 or 2 arsenical injections; only 12 received as many as 10." The "untreated" group in this study is therefore a group of treated *and* untreated male subjects.

5. There is evidence that control subjects who became syphilitic were transferred to the "untreated" group. This data is present in the patient files at the Center for Disease Control in Atlanta. Caldwell⁸ reports 12 original controls either acquired syphilis or were found to have reactive treponemal tests (unavailable prior to 1953). Heller,⁶ also, reported that "It is known that some of the control group have acquired syphilis although the exact number cannot be accurately determined at present." Since this transfer of patients from the control group to the syphilitic group did occur, the study is not one of late latent syphilis. Also, it is not certain that this group of patients did in fact receive adequate therapy.

6. In the absence of a definitive protocol, there is no evidence or assurance that standardization of evaluative procedures, which are essential to the validity and reliability of a scientific study, existed at any time. This fact leaves open to question the true scientific merits of a longitudinal study of this nature. Standardization of evaluative procedures and clinical judgment of the investigators are considered essential to the valid interpretation of clinical data.⁹ It should be noted that, in 1932, orderly and well planned research related to latent syphilis was justifiable since a. Morbidity and

mortality had not been documented for this population and the significance of the survey procedure had just been reported in findings of the prevalence studies for 6 southern counties;¹ b. Epidemiologic knowledge of syphilis at the time had not produced facts so that it could be scientifically documented "just how and at what stage the disease is spread."* c. There was a paucity of knowledge re clinical aspects and spontaneous cure in latent syphilis³ and the Oslo study⁴ had just reported spontaneous remission of the disease in 27.7% of the patients studied. If perhaps a higher "cure" rate could have been documented for the latent syphilitics, then the treatment priorities and recommendations may have been altered for this community where funds and medical services were already inadequate.

The retrospective summary of the "Scientific Contributions of the Tuskegee Study" from the Chief, Venereal Disease Branch, USPHS (dated November 21, 1972) includes the following merits of the study:

"Knowledge already gained or potentially able to be gained from this study may be categorized as contributing to improvements in the following areas:

1. Care of the surviving participants,
2. Care of all persons with latent syphilis,
3. The operation of a national syphilis control program,
4. Understanding of the disease of syphilis,
5. Understanding of basic disease producing mechanisms."

Panel Judgments on Charge 1-A

1. In retrospect, the Public Health Service Study of Untreated Syphilis in the Male Negro in Macon County, Alabama, was ethically unjustified in 1932. This judgment made in 1973 about the conduct of the study in 1932 is made with the advantage of hindsight acutely sharpened over some forty years, concerning an activity in a different age with different social standards. Nevertheless one fundamental ethical rule is that a person should not be subjected to avoidable risk of death or physical harm unless he freely and intelligently consents. There is no evidence that such consent was obtained from the participants in this study.

2. Because of the paucity of information available today on the manner in which the study was conceived, designed and sustained, a scientific justification for a short term demonstration study cannot be ruled out. However, the conduct of the longitudinal study as initially reported in 1936 and through the years is

*Letter from L. Usilton, VD Program 1930-32 and memorandum from Vonderlehr to T. Clark (Assistant Surgeon General) June 10, 1932.

*Vonderlehr to T. Clark — Memorandum — June 10, 1932.

judged to be scientifically unsound and its results are disproportionately meager compared with known risks to human subjects involved. Outstanding weaknesses of this study, supported by the lack of written protocol, include lack of validity and reliability assurances; lack of calibration of investigator responses; uncertain quality of clinical judgments between various investigators; questionable data base validity and questionable value of the experimental design for a long term study of this nature.

The position of the Panel must not be construed to be a general repudiation of scientific research with human subjects. It is possible that a scientific study in 1932 of untreated syphilis, properly conceived with a clear protocol and conducted with suitable subjects who fully understood the implications of their involvement, might have been justified in the pre-penicillin era. This is especially true when one considers the uncertain nature of the results of treatment of late latent syphilis and the highly toxic nature of therapeutic agents then available.

REPORT ON CHARGE I-B

Statement of Charge I-B: Determine whether the study should have been continued when penicillin became generally available.

Background Data

In 1932, treatment of syphilis in all stages was being provided through the use of a variety of chemotherapeutic agents including mercury, bismuth, arsphenamine, nearsphenamine, iodides and various combinations thereof. Treatment procedures being used in the early 1930's extended over long periods of time (up to two years) and were not without hazard to the patient.¹⁰ As of 1932, also, treatment was widely recommended and treatment schedules specifically for late latent syphilis were published and in use.^{3 10} The rationale for treatment at that time was based on the clinical judgment "that the latent syphilitic patient must be regarded as a potential carrier of the disease and should be treated for the sake of the Community's health."³ The aims of treatment in the treatment of latent syphilis were stated to be: 1) to increase the probability of "cure" or arrest, 2) to decrease the probability of progression or relapse over the probable result if no treatment were given and 3) the control of potential infectiousness from contact of the patient with adults of either sex, or in the case of women with latent syphilis, for unborn children.

According to Pfeiffer (1935),¹¹ treatment of late syphilis is quite individualistic and requires the physician's best judgment based upon sound fundamental knowledge of internal medicine and experience, and should not be undertaken as a routine procedure. Thus, treatment was being recommended in the United States for all stages of syphilis as of 1932 despite the "spontaneous" cure concept that was being justified by interpretations of the Oslo study, the potential hazards of treatment due to drug toxicity and to possible Jarisch-Herxheimer reactions in acute late syphilis.¹²

Documented reports of the effects of penicillin in the 1940's and early 1950's vary from outright support and endorsement of the use of penicillin in late and latent syphilis,¹³⁻¹⁵ to statements of possible little or no value,¹⁶⁻¹⁷ to expressions of doubts and uncertainty¹⁸⁻¹⁹ related to its value, the potency of penicillin, absence of control of the rate of absorption, and potential hazard related to severe Herxheimer effects.

Although the mechanism of action of penicillin is not clear from available scientific reports of late latent syphilis, the therapeutic benefits were clinically documented by the early 1950's and have been widely

reported from the mid 1950's to the present. In fact, the Center for Disease Control of the USPHS has reported treatment of syphilitic mothers in all stages of infection with penicillin as of 1953²⁰ and has demonstrated that penicillin is the most effective treatment yet known for neurosyphilis (1960).²¹

Facts and Documentation re Charge I-B

1. Treatment schedules recommending the use of arsenicals and bismuth in the treatment of late latent syphilis were available in 1932.³ Penicillin therapy was recommended for treatment of late latent syphilis in the late 1940's¹⁴⁻¹⁵ which was *before* it became readily available for public use (estimated to have been 1952-53).

2. It was "known as early as 1932 that 85% of patients treated in late latent syphilis would enjoy prolonged maintenance of good health and freedom from disease as opposed to 35 percent if left untreated."³ Scientists in this study,⁵ reported in 1936, that morbidity in male Negroes with untreated syphilis far exceeds that in a comparable nonsyphilitic group and that cardiovascular and central nervous system involvements were two to three times as common. Moreover, Wenger,²² in 1950, reported: "We know now, where we could only surmise before, that we have contributed to their ailments and shortened their lives. I think the least we can say is that we have a high moral obligation to those that have died to make this the best study possible." The effect of syphilis in shortening life was published from observations made by Usilton et al. in 1937.²³ The study by Rosahn²⁴ at Yale in 1947 reported strong clinical evidence that syphilis ran a more fatal course in Negroes than in Caucasians.

3. Reports regarding the withholding of treatment from patients in this study are varied and are still subject to controversy. Statements received from personal interviews conducted by Panel members with participants in this study cannot be considered as conclusive since there are varied opinions concerning what actually happened. In written letters and in open interviews, the panel received reports that treatment was deliberately withheld on the one hand and on the other, we were told that individuals seeking treatment were not denied treatment (in transcript and correspondence documents).

What is clearly documentable (in a series of letters between Vonderlehr and Health officials in Tuskegee taking place between February 1941 and August 1942) is that known seropositive, untreated males under 45 years of age from the Tuskegee Study had been called for army duty and rejected on account of a positive blood. The local board was furnished with a list of 256

names of men under 45 years of age and asked that these men be excluded from the list of draftees needing treatment! According to the letters, the board agreed with this arrangement in order to make it possible to continue this study on an effective basis. It should be noted that some of these patients had already received notices from the Local Selective Service Board "to begin their antisyphilitic treatment immediately."

According to Wenger,²² the patients in the study "received no treatment on our recommendation." At the present time, we know that most of the participants in this study received some form of treatment with heavy metals and/or antibiotics.⁸ Although the adequacy of treatment received is not known, it is clear that the treatment received was provided by physicians who were not a part of the study and who were individually sought by the individual patients related to their own medical symptoms and pursuit of treatment.

4. The five survey periods in this study occurred in 1932, 1938-39, 1948, 1952-53 and 1968-70.⁸⁻²⁵ This study lacks continuity except through the public health nurse and at these isolated survey periods. In 1969 an Ad Hoc Committee reviewed the Tuskegee Study with the purpose: to examine data from the Tuskegee Study and offer advice on continuance of this study.

Participants of the February 6, 1969 meeting included:

Committee Members:

Dr. Gene Stollerman
Chairman, Dept. of Medicine
University of Tennessee, Memphis

Dr. Johannes Ipsen, Jr.
Professor
Dept. of Community Medicine
University of Pennsylvania, Philadelphia

Dr. Ira Myers
State Health Officer
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Dr. J. Lawton Smith
Associate Professor of Ophthalmology
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Resource Persons:

Dr. Bobby C. Brown, VDRL, NCDC
Mrs. Eleanor V. Price, VD Branch, NCDC
Dr. Joseph Caldwell, VD Branch, NCDC
Dr. Paul Cohen, VDRL, NCDC
Dr. Sidney Olansky

Professor of Medicine
Dept. of Internal Medicine
Emory University Clinic, Atlanta

Recorders:

Dr. Leslie C. Norins
Chief, VDRL, NCDC

Mrs. Doris J. Smith
Secretary to Dr. Norins, VDRL, NCDC

Attending:

Dr. David J. Sencer
Director, NCDC

Dr. William J. Brown
Chief, VD Branch, NCDC

Dr. U.S.G. Kuhn, III, VDRL, NCDC
Miss Genevieve W. Stout, VDRL, NCDC

Dr. H. Bruce Dull
Assistant Director, NCDC

The meeting was convened at 1:00 p.m. and adjourned at 4:10 p.m.

A summary report of the meeting includes the following:

The purpose of the meeting was to determine if the Tuskegee Study should be terminated or continued.

Considerations were:

1. How the study was setup in 1932
2. Are the participants all available
3. How are the survivors faring

At the time of this study there were only seven patients whose primary cause of death was ascribed to syphilis.

It was determined that benefits to be achieved from the study at this time were:

1. Relationship of serology to morbidity from syphilis
2. Relationship of known pathology to syphilis
3. Various epidemiological considerations

Full treatment of the survivors was also considered and the following liabilities listed.

Danger of late Herxheimer's reaction which would worsen or possibly kill those syphilitic patients suffering from cardiovascular or neurological conditions.

At this time it was mentioned that both Macon County Health Department and Tuskegee Institute were cognizant of the study.

The meeting was terminated with several salient points.

1. This type of study would never be repeated.
2. There were certain medical facts to be learned by continuing the present study.
3. Treatment for these patients was not indicated unless they had signs of active syphilitic disease.
4. More contact should be established between PHS and Macon County Health Department and Medical Society so they would cooperate in the continuance of the study.

It should be noted that the Committee was eminently represented from the medical community. However, legal representatives and others from the non-medical community of scholars were not adequately represented for so sensitive a study. This is especially true since the Tuskegee Study was being continued at a time when Department of Health, Education, and Welfare guidelines for the Protection of Human Subjects were being widely disseminated for compliance by all institutions receiving grant support. The three hours and ten minutes were not adequate for in-depth study of the broad issues, implications and ramifications of this study.

In 1970, Drs. Anne Yobs and Arnold L. Schroeter in separate memoranda (to the Director, Center for Disease Control and to the Chief, Venereal Disease Branch) recommended procedures for orderly termination of this study. Dr. James Lucas, Assistant Chief of the Venereal Disease Branch, in a memorandum to the Chief of the Venereal Disease Branch dated September 10, 1970

states: It must be fully realized that the remaining contribution from this study will be largely of *historical* interest. Nothing learned will prevent, find, or cure a single case of infectious syphilis or bring us closer to our basic mission of controlling venereal disease in the United States.

5. There is a crucial absence of evidence that patients were given a "choice" of continuing in the study once penicillin became readily available. This fact serves to amplify the magnitude of encroachment on the human lives and well-being of the participants in this study. This is especially significant when there is uncertainty as to the whole issue of "consent" of the participants.

Panel Judgments on Charge I-B

The ethical, legal and scientific implications which are evoked from the facts presented in the previous section led the Panel to the following judgment:

That penicillin therapy should have been made available to the participants in this study especially as of 1953 when penicillin became generally available.

Withholding of penicillin, after it became generally available, amplified the injustice to which this group of human beings had already been subjected. The scientific merits of the Tuskegee Study are vastly overshadowed by the violation of basic ethical principles pertaining to human dignity and human life imposed on the experimental subjects.

REPORT ON CHARGE I

SUMMARY

This section of the Advisory Panel's report deals specifically with Charge Codes I-A and I-B.

Statement of Charge Codes

Charge I-A. Determine whether the study was justified in 1932, and

Charge I-B. Determine whether it should have been continued when penicillin became generally available.

Introduction

The Background Paper on the Tuskegee Study, prepared by the Venereal Disease Branch of the Center for Disease Control, July 27, 1972, included the following statements:

"Because of the lack of knowledge of the pathogenesis of syphilis, a long-term study of untreated syphilis was considered desirable in establishing a more knowledgeable syphilis control program."

"A prospective study was begun late in 1932 in Macon County, Alabama, a rural area with a static population and a high rate of untreated syphilis. An untreated population such as this offered an unusual opportunity to follow and study the disease over a long period of time. In 1932, a total of 26 percent of the male population tested, who were 25 years of age or older, were serologically reactive for syphilis by at least two tests, usually on two occasions. The original study group was composed of 399 of these men who had received no therapy and who gave historical and laboratory evidence of syphilis which had progressed beyond the infectious stages. A total of 201 men comparable in age and environment and judged by serology, history, and physical examination to be free of syphilis were selected to be the control group."

Panel Conclusions re Charge I-A and I-B of the Tuskegee Study

After extensive review of the available documents, interviews with associated parties and pursuit of various other avenues of documentation, the Panel concludes that:

1. In retrospect, the Public Health Service Study of Untreated Syphilis in the Male Negro in Macon County, Alabama was ethically unjustified in 1932.
2. Because of the paucity of information available today on the manner in which the study was conceived, designed and sustained, scientific justification for a short-term demonstration study in 1932 cannot be ruled

out. However, the conduct of the longitudinal study as initially reported in 1936 and through the years is judged to be scientifically unsound and its results are disproportionately meager compared with known risks to the human subjects involved.

3. Penicillin therapy should have been made available to the participants in this study not later than 1953.

The Panel qualifies its conclusions with several position statements summarized as follows:

a. The judgments in 1973 about the conduct of the Tuskegee Study in 1932 are made with the advantage of hindsight, acutely sharpened over some forty years concerning an activity in a different age with different social standards. Nevertheless one fundamental ethical rule is that a person should not be subjected to avoidable risk of death or physical harm unless he freely and intelligently consents. There was no evidence that such consent was obtained from the participants in this study.

b. History has shown that certain people under psychological, social or economic duress are particularly acquiescent. These are the young, the mentally impaired, the institutionalized, the poor and persons of racial minority and other disadvantaged groups. These are the people who may be selected for human experimentation and who, because of their station in life, may not have an equal chance to withhold consent.

c. The Tuskegee Syphilis Study, placed in the perspective of its early years, is not an isolated event in terms of the generally accepted conditions and practices that prevailed in the 1930's.

d. The position of the Panel must not be construed to be a general repudiation of scientific research with human subjects. It is possible that a scientific study in 1932 of untreated syphilis, properly conceived with a clear protocol and conducted with suitable subjects who fully understood the implications of their involvement, might have been justified in the pre-penicillin era because of the uncertain nature of results of treatment of late latent syphilis with the highly toxic therapeutic agents then available.

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Respectfully Submitted,

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Approval with Reservations:

(See addendum for reservation statement)

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