



The Contribution of the Tuskegee Study to Medical Knowledge*

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WHEN invited by Dr. Vernal Cave, local chairman for the Dermatology section of the National Medical Association, to outline the contribution of the "Tuskegee Study" to medical knowledge, I accepted his invitation with some enthusiasm, and a great deal of reluctance. Enthusiasm because I felt that acceptance of his invitation would serve as a stimulus to me as a physician, scientist, and educator to look at the accumulated data that have risen from the study and then draw my own conclusions as to the scientific importance of this long-term study of untreated syphilis. Reluctance because I felt that it would be difficult for me as a black physician to dissociate in my mind the scientific merits of the study from my emotional or gut responses to it, and that it would be difficult for me to present clearly the facts as I see them, in an unbiased manner, such that other black physicians would be able to draw their own conclusions when my material is presented to them. Because I was committed, though reluctantly, I plunged forthrightly into the task and will present to you the facts as I see them.

My approach to the topic "The Contribution of the Tuskegee Study to Medical Knowledge" is that of a physician-investigator who has been actively engaged, for over 10 years, in experimen-

tion on human subjects. My interpretations and conclusions, I trust, will be as unemotional and unbiased as is humanly possible.

To place my remarks in perspective, the reader should be given some insight into the extent of my perusal of the literature. I have reviewed all of the reports published from 1936-1963 which pertain to the "Tuskegee Study."¹⁻¹² I have also reviewed several written reports on the Oslo Study by Bruusgaard,¹³⁻¹⁶ the "Oslo Study" of Gjestland,¹⁷ and the reports of Rosahn¹⁸⁻²⁰ and others which were considered by syphilologists as being of importance in establishing the scientific necessity and merits of the "Tuskegee Study." I have also attempted to consider the merits of the design of the "Tuskegee Study" in light of the scientific standards of the early 20th century and those established in the latter half of the same century.

What was the medical justification for the study? Was it necessary to study the natural course of syphilis in 1932 in the light of available data? The stated purpose of the "Tuskegee Study" was to compare health and longevity of an untreated syphilis population with an otherwise similar non-syphilitic population. One may cite the lack of good immediate therapy such as penicillin when the study was initiated. There were questions as to the severity of untreated syphilis, particularly in view of the hazards of syphilis therapy as prac-

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ticed in 1930. There were also controversies over the successfulness of syphilis treatment in the 1930's.

Kampmeier in 1943 stated that "it would be of great value if the prognosis in untreated syphilis were accurately known."²¹ Stokes in 1944, 12 years after the initiation of the "Tuskegee Study" states that ". . . the great ailment of modern syphilitological practice is a lack of comprehension of the why and wherefore, rather than the what to do."²² Clark and Danbolt, in 1955, in an interpretation of Stokes' quotation, 22 years after the initiation of the "Tuskegee Study," state that "comprehension of the 'why' and 'wherefore' lay in a better understanding of the prognosis of untreated syphilis. The beneficial effects of treatment in modifying the biological course of syphilis infections is well known. . . . lacking is quantitative information on what happens to those who go untreated. The reason for this lack lay in the absence of studies of large groups of untreated patients, thoroughly diagnosed and observed over sufficient periods of time." The Boeck material (and the Tuskegee material) provided such a group of patients.²³

Gjestland in his monograph on a re-study of the Boeck-Bruusgaard material indicates that there are "three (basic) methods or techniques by which information on the outcome of untreated syphilis may be obtained"¹⁷: these are;

1. From anamnestic data obtained from patients seen for the first time in late stages of syphilis. Many contributions to the literature present such groups of patients and attempt to draw sweeping conclusions as to effects of various amounts of treatment or no treatment.

2. From a specific group of untreated patients studied in retrospect such as the Bruusgaard study.

3. From a retrospective plus a prospective <<no treatment>> study such as the <<Alabama (Tuskegee)>> studies.

4. To these may be added a fourth technique, that used by Rosahn (1947) in his interesting <<Autopsy Studies in Syphilis>>.

Shafter et al., reported in 1954 that in spite of the large number of reported studies on syphilis in the English and European literature there were, in 1930, no "accurate data relative to the effect of syphilis in shortening life span. There were no accurate data on the natural history of the disease leading up to the complications in the cardiovascu-

lar, and central nervous systems."⁸ They go on to state that this information was necessary "to evaluate the effectiveness of programs of public health control with a reasonable degree of understanding of the natural history of the disease." Of those commenting on the need for such studies, only Shafter et al. were directly or indirectly involved in either the "Tuskegee or Oslo Study."

Why, in the light of the previously published Bruusgaard Study of the Boeck material, was it necessary to initiate the "Tuskegee Study?"

Before attempting to answer this question, one should become familiar with the Boeck-Bruusgaard material and the subsequent "Oslo Study" report²⁴ i.e., the completeness of the study, the conclusions drawn from the study and the many overlooked criticisms of the study, including some by Bruusgaard himself.

From 1890 to 1910, Caesar Boeck, chief of the Syphilis Clinic at the University Hospital, Oslo, Norway, and subsequently professor of venereology and dermatology, University of Oslo, hospitalized approximately 2,000 patients with primary and secondary syphilis until the lesions healed without specific treatment. These patients, by and large, came from the east side of Oslo and represented, in most instances, the lowest socioeconomic segment of society in Oslo. Cutaneous lesions were carefully described on admission to the hospital and regression and time of disappearance was noted in carefully kept records. Serological tests were not performed since none were available. Diagnosis rested purely on clinical observations. [Boeck did not treat his patients because, unlike his Norwegian contemporaries, he felt that ultimately the host defenses were sufficient to ward off the ravages of syphilitic infection. Treatment, he felt should be confined to the stimulation of the host's immune mechanisms.¹⁷]

Bruusgaard, Boeck's assistant, and successor, began in 1925 a follow up study of Boeck's former patients. The purpose of his study was to show "how syphilis progresses when little or no treatment is given and the patient's defense mechanisms were left to combat the disease alone."²⁴ This study culminated in the publication of the now famous "Oslo Study" which became available in 1929. Several conclusions were drawn from Bruusgaard's report of his study in 1929. The substance of these conclusions will be discussed and contrasted with findings in the "Tuskegee Study."

In spite of many criticisms of Bruusgaard's Oslo Study by eminent syphilologists of the day, his data were accepted as the best available material on untreated syphilis. Clark and Danbolt's comments in 1954 regarding the Bruusgaard study reads as follows: "As these estimates of prognosis have passed from textbook to textbook and from one scientific paper to another, they have taken on a significance entirely unwarranted by the nature of Bruusgaard's data."²³ Bruusgaard himself warned that acceptance of his data should be made "with the reservation which the nature of his material makes necessary."¹⁷

Among many defects cited in Bruusgaard's study that invalidated or limited its usefulness are: *a*) The study was a retrospective study and as such could not support or refute an hypothesis. It could only provide clues to the directions a well-planned prospective study should take. *b*) Only 20% of Boeck's original group of patients were located. This group of 473 patients formed the basis of the often quoted Oslo Study. *c*) Only a portion of the 473 patients were seen and examined by Bruusgaard. Most of the patients' information came from records of subsequent hospitalizations, autopsy records, etc. *d*) Since most of his material related to hospitalized patients, his sample was highly selected and was not representative of Boeck's original group. In fact, Sowder wrote in 1940 that "the direction of (Bruusgaard's) selection has been to exaggerate the seriousness of the disease rather than to minimize it."¹⁶ For example, Bruusgaard is accused of searching out only those patients in Boeck's group who may have had central nervous system disease of sufficient severity to warrant hospitalization or institutional care. *e*) Since all of Boeck's patients were selected on the basis of clinical findings (serological tests were performed on none, and dark field examinations were performed in only a phase of the original study), it is not possible to determine the accuracy of the original diagnosis in many cases. *f*) Was the course of the disease in those examined the same as in those who were lost from observation? *g*) The study was too liberal in attributing a physical or pathological abnormality to syphilis.

Venereologists cited these defects in the "Oslo Study" as making for misinterpretation of the natural course of untreated syphilis. Therefore, a well planned prospective study, such as the "Tuskegee Study" could have been, was sorely needed.

It may be well to mention here that the "Oslo Study" and the "Tuskegee Study" patient populations represent the only two groups of patients who have been deliberately denied treatment for active syphilis. They differ, however, in *a*) the composition of their patient population; i.e., the "Tuskegee Study" was concerned with the late effects of untreated syphilis in a black male population; and the "Oslo Study" was concerned with the late effects of syphilis in a white male and female population. *b*) The stage of disease at the initiation of the study differed; i.e., the "Tuskegee Study" involved black males with latent untreated syphilis (all persons examined and having early syphilis were treated and excluded from the study); the "Oslo Study" involved persons with early (primary and secondary) untreated syphilis.

To my knowledge there were no other significant studies on the effects of untreated syphilis until Roshan's 1947 "Autopsy Studies in Syphilis,"¹⁸ and Gjestland's 1955 "Oslo Study of Untreated Syphilis."¹⁷

What are some of the major scientific criticisms of the "Tuskegee Study?"

A. The absence of a clearly defined protocol in a scientific study of such importance. I cannot write with authority regarding medical-scientific practices of the early part of the 20th century, however, after scanning the medical-scientific literature of the early half of the century, I became impressed with the absence in most reports of well-planned scientific methodology. The "Tuskegee Study" reports, by and large, fall into this category. Based on my observations, I think it would be safe to say that true scientific medicine did not have its birth until the mid 20th century.

B. The lack of informed consent. Informed consent, as a dominant legal doctrine is a product of the latter half of the 20th century, and even now the extent to which patients are truly informed is questionable. Many well established investigators are being accused of deliberately misleading patient volunteers, often taking advantage of their (patients') ignorance, economic status or the emergency nature of their disease.

Some critics of present day practices, who, by the way, agree that human experimentation is a worthwhile endeavor, and that human experimentation has contributed greatly to the advancement of modern medicine, feel that in order for the concept of informed consent to be a valid concept,

socially and/or economically impoverished and uneducated persons should not be selected as subjects for research, since only the most educated in a population are capable of giving their informed consent.

Given these criteria for the selection of patient material in the 1930's, the "Tuskegee Study" would never have taken place.

C. Changes in key personnel over the years in a long range project, without a clearly defined protocol and standardization procedures, seriously weakened the continuity and thus the contribution of the study to medical knowledge. Dr. J. J. Peters, radiologist and pathologist, was to my knowledge, the only physician to remain a continuing member of the study group for a meaningful period of time.

D. The "Tuskegee Study" group consisted of black males only. In order for the study to be valid, not only should there have been an additional study involving black females, but white males and females also. This criticism is strengthened by the fact that in the 1930's there were thought to be great differences in the outcome of untreated syphilis in whites versus blacks, and males versus females.

E. The study may have been biased in favor of the cardiovascular examination from the second examination on. This bias was thought to be related to the purported high incidence of cardiovascular syphilis in blacks with latent syphilis, and the envisioned need to clarify the clinical diagnosis of early uncomplicated syphilitic aortitis.

F. Since all of the patients in the "Tuskegee Study" were culled from a population of latent syphilitics, the duration of their infection was not known.

What did the "Tuskegee Study" contribute to medical knowledge?

In contrast to the opinions of many physicians and syphilologists, it is my opinion that the "Tuskegee Study", in spite of its many weaknesses, did make significant contributions to medical knowledge as it pertains to syphilology. In order to appreciate this fact, one has to contrast the findings reported in this study with those reported in the more famous, but probably less contributory, Bruusgaard "Oslo Study",²⁴ the 1947 "Autopsy Studies of Rosahn",¹⁸ and Gjestland's 1955 "Re-study of the Boeck-Bruusgaard material".¹⁷

I will begin this contrast with the Bruusgaard

"Oslo Study". The significant findings in that study are as follows: (This study included 473 of Boeck's original group of patients. Three hundred and nine were living and 164 were dead, 40 of whom were autopsied).

1. 28% of the patients were clinically free from symptoms and were serologically negative.

2. 14.8% had no clinical symptoms of systemic infection but were serologically positive.

3. 23% had clinical or autopsy evidence of syphilitic pathology of a serious nature. Among these:

14% had cardiovascular disease

2.8% had general paresis

1.3% had tabes dorsalis

Bruusgaard's conclusions from these data are as follows:¹⁷

"Syphilis is a disease which is accompanied by severe complications as early as in its secondary stage. Eye and ear affections are here the most frequent. . . ; there are often symptoms of a meningeal disease."

"Far more important, however, are the late syphilitic diseases. First among these are affections of the heart and blood vessels . . . parenchymatous syphilis of the central nervous system lies far behind."

"Neither do tertiary eruptions of the skin, mucous membranes and bones give particularly high figures . . . (in latent infection)."

In summary, Bruusgaard's study suggested: *a*) a probability of spontaneous cure; *b*) continued latency; and *c*) the potential for a serious fatal outcome in a number of untreated syphilitics.

Let us contrast the significance of these findings with those reported in a series of articles entitled "Untreated Syphilis in the Male Negro".¹⁻¹² The case material in these reports comprised the Tuskegee Study Group. Four hundred and twelve black male residents of Macon County, Alabama were found to have latent syphilis on serological examination. Anti-syphilis treatment was withheld, if at all possible, from these subjects from 1932. One hundred and ninety-two black males without serological evidence of syphilis were used as controls.

The data from these reports may be summarized as follows:

1. Vonderlehr et al. in the first report dated September 1936, or four years after initiation of the study, noted that the morbidity or rate of ill-

ness of a nonspecific nature experienced in the untreated population approached 84%. In the control group, a figure of 39% was given.¹ The effect of syphilis in producing morbidity in early life was especially noted. In patients under 40, only 20% showed no evidence of morbidity in either the cardiovascular and central nervous systems, in the bones, eyes, gastrointestinal, respiratory and genito-urinary systems.

Of particular interest was the finding of some form of central nervous system disease in 26% of the untreated syphilitics, 7.8% of whom had definite clinical evidence of disease. This, in spite of previously held beliefs that neurosyphilis was almost nonexistent in blacks.

Eleven and a half % of the group was found to have disease in the bones, joints and skin.

2. Approximately 10 years later, in 1946, Heller, Bruyere, Smith and Usilton reported on the mortality rate in untreated versus treated syphilis, and in the group of control black males.^{2,25, 26} They reported "it will be seen at once that there was a much greater mortality among the syphilitics than among the controls", 24.6% versus 13.9%. The syphilitic individual had a much shorter life expectancy than the normal controls. The critical periods appeared to occur between the ages of 27-34 and 45-55. At age 25 syphilis shortened the life of its hosts by almost 40 percent. Overall life expectancy was 20% less than in the control population.

In a study of treated syphilis and life expectancy, Smith et al. noted that "the average life span of persons under routine therapy for syphilis is shorter than that of the uninfected persons".²⁵

3. In 1946, Deibert reported on the cardiovascular findings in the untreated versus control group.³ He noted that there was a set of definite clinical findings that may be obtained by history, physical and fluoroscopic examination which when correlated could result in an earlier diagnosis of cardiovascular syphilis, especially uncomplicated syphilitic aortitis.

He noted that syphilitics showed more dilatation of the aorta than controls. Both the systolic and diastolic blood pressures were higher than in controls. (Syphilis had not previously been implicated as a significant etiological factor in hypertension.) The percentage of syphilitics in which evidence of arteriosclerosis could be detected was significantly greater than in the controls.

An additional finding in every age group examined was the increased numbers of syphilitics showing pathological changes in the lymph nodes.

4. Peters et al. in 1954 reported on some of the most significant data obtained in the "Tuskegee Study".⁸ Significant, because all of the examination data accumulated for this report, which included fluoroscopic examinations, gross autopsy examinations, and examination of all histological specimens, were performed by one physician. In the period from 1932 to 1952, 40% of the syphilitics versus 20% of the controls had died. It was noted that most of the lesions that could be attributed to syphilitic involvement were found in the cardiovascular system. Grossly, syphilitic aortitis was diagnosed in 40% of those autopsied. Of 24 patients spontaneously returning to a negative serological examination, only two had macro- and microscopic evidence of aortitis. Peters felt that his findings suggested that a "black" male with syphilis of more than 10 years duration, for which he has received no therapy and has a sustained seropositivity prior to death, would have roughly a 50-50 chance of demonstrating syphilitic cardiovascular involvement at autopsy.

He also noted that clinical evidence of aortitis was not confirmed on gross examination and histopathology in 19 patients, indicating that clinical efforts at that time were inadequate to some degree in aiding in determining etiology of aortitis.

Peters and his associates believed that the primary cause of death in 30% of the infected, untreated group could be attributed to syphilitic involvement of the cardiovascular or central nervous system.

5. Olansky and co-workers, in 1954, reported on the environmental factors in untreated syphilitics.⁷ In this study, Olansky reported that the family status, community activities, housing status, work status, dietary status, and relative economic status of the untreated syphilitic population and the control group were clearly the same. The results of this study clearly implied that in this population group excess mortality and morbidity could not be attributed to differences in socioeconomic status. Prior to this report it had been noted that there were socioeconomic differences in prevalence of syphilis and thus it was concluded that syphilis morbidity and mortality were directly related to socioeconomic factors rather than to non-specific factors in disease; i.e., the same condi-

tions that foster high prevalence rates for syphilis, foster high mortality rates from all causes.²⁷ It may be of interest to note that Rosahn reported in 1952 his findings on longevity in a group of white mice infected with *Treponema pallidum*.²⁰ It was his impression that a group of infected mice reared under the same circumstances as an uninfected group of mice suffered an adverse effect on longevity that could be directly related to non-specific factors in the treponemal disease.

6. In another report Olansky and co-workers reported that even a small amount of treatment, if given to syphilitic patients whose disease duration was less than 15 years, would influence the outcome of the serological tests for syphilis.¹¹ They also noted that 27% of the patients with spontaneous serological reversal had some clinical manifestations of late syphilis.

7. Thirty years after the initiation of the study, Rockwell and associates reported that after age 55 "it appears that the process of aging emerges as a significant factor in causes of death in the syphilitics as well as the control group."¹²

They also reported that by 1939, 42% of the surviving untreated group had received some form of treatment, making continuation of the study questionable in at least a portion of the group. By 1963, 30 years after the initiation of the study, 77% of the survivors had received some form of therapy. The fact that 77% of the surviving members of the group had received some form of therapy, indicates to me that some form of treatment, no matter how little, is better than none.

Some of the most significant information coming from the Rockwell study relates to the comparative reliability of the various serologic tests for syphilis in detecting latent syphilis:

- 65% of the surviving group of 93 has positive VDRL's.
- 52% were reactive by the Kolmer Reiter Protein test.
- 89% were reactive by the TPI test, and
- 94.5% were reactive by the FTA-ABS test.

The FTA-ABS test was positive in four cases in which the TPI was negative, and reactive 12 times when the VDRL was negative. Thus indicating the superior reliability of the FTA-ABS test.

Space does not permit me to contrast fully the findings of the "Tuskegee Study" with those of Gjestland's 1955, "Re-study of the Boeck-Bruusgaard Material" or Rosahn's 1947 "Autopsy

Studies of Untreated Syphilis."¹⁷⁻¹⁸ However, I believe I am correct in stating that there are just as many criticisms of the scientific methodology in these studies as there are of the "Tuskegee Study." By and large these studies merely corroborate the findings in the earlier "Tuskegee Study."

In my opinion the greatest contribution of the "Tuskegee Study" lies not in the scientific merit of the publications that have emanated from it, but in the anguish and concern its revelation has provoked in the minds of lay persons, physicians, medical investigators and others. The degree of anguish and concern has been such that our entire nation has been stimulated to rethink and redefine our present day positions and practices as they relate to human experimentation.

In closing, it is apparent that in spite of its sociological, moral and scientific shortcomings, when compared with the more often quoted studies of a similar nature, the "Tuskegee Study did contribute a considerable amount of information to medical knowledge." I will not go so far as to agree entirely with Gjestland's 1955 comments, that "there is little doubt that the <<Alabama Study>> is the best controlled experiment ever undertaken in this particular field."¹⁷ However, I do feel that as we should not let our concern for the immorality of this study die, we should not let our present sensitivities obscure the fact that this study has contributed and can continue to contribute a great deal to our knowledge of syphilology.

Black physicians, in particular should be determined to see to it that the contributions made by our black brothers in Macon County, Alabama, not be permitted to lie dormant, but be revived, reassessed and used in a meaningful way to aid in combatting the ravages of syphilis and related diseases as yaws, bejel, etc. which continue to have a high degree of prevalence throughout the continent of Africa and many of the underdeveloped equatorial countries.

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(Secundy and Lloyd, from page 88)

From a student assigned to a private physician: "I find that my view of the physician is changing, almost daily. He is no longer an isolated entity who just writes prescriptions. I am beginning to see that he has to be a social innovator. . . ."

In summary, freshmen and sophomore medical students at Howard University College of Medicine are now being exposed to direct patient care and introduced to various facets of health care through the Clinical Medical Preceptorship Program coordinated and administered by the Department of Family Practice.

The Preceptorship, required of all freshmen and sophomore students, is being well received by both students

and participating preceptors. The program draws upon the resources of private physicians, health care administrators, public health professionals, allied health professionals, and voluntary health agencies. Students are demonstrating the relevancy of such a course by making correlations between clinical medicine and their basic science courses. They are obtaining initial skills in history taking and physical diagnosis. More importantly, they are learning about the problems of health care delivery, are able critically to analyze these problems, and are projecting to their future roles as physicians who must assume major leadership roles in addressing these problems.