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API-59

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Kettering Laboratory

University of Cincinnati

THE PROJECT ON CARCINOGENICITY

PROPOSED EPIDEMIOLOGICAL STUDIES

Progress Report

for

The Subcommittee on Carcinogenicity

of the

API Medical Advisory Committee

April 23, 1950

Revision - May 15, 1950

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PRESENT STATUS

At the Subcommittee meeting held March 25, 1950, the following objectives were presented:

I. The determination of incidence and prevalence rates of retrograde, hypertrophic or neoplastic reactions in employees of the Petroleum Industry.

II. The comparison of these rates with those of the general population and other industries.

III. The evaluation of control procedures that have been accepted, employed or recommended.

IV. The recommendation, if the studies justify the action, of standardized safety and control measures.

The possible approaches to these objectives are:

I. A Retrospective or Historical Study of all available records of such cases among the employees of the Petroleum Industry.

II. A Current Registry receiving reports of such cases as they are discovered by and/or reported to the various Medical Departments.

III. A study of the Employee Health Benefit Plan records with the hope that like data can be secured from other industries.

IV. Field Surveys of retrograde or hyperkeratotic lesions on exposed skin surfaces.

V. A repetition of the studies which have pointed out an unusual hazard in the Slack Wax Process.

VI. The establishment of a Consultation Service to assist in the planning of comparable company studies. This last approach was not discussed at the Cincinnati meeting.

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FUTURE PLANS

A. It is proposed to implement immediately, insofar as possible and/or feasible, with due consideration and understanding of the wide variation in company policies, medical care programs, management interest and labor relations, the first two approaches, namely, (I) the Retrospective Study and (II) the Current Registry.

I. Retrospective or Historical Study

1. Description

This approach requires the assembling of the clinical records and employment histories of proved cases of Neoplastic disease known to have occurred among employees of the cooperating Petroleum Companies, regardless of site, type of tumor, degree of exposure to various carcinogenic hazards and employment status.

The Medical Departments, under this plan, within the limits of their legal responsibilities (See Appendix, Page 1), would be expected to forward to the Survey Group of the University of Cincinnati the records of all known cases of proved or suspected Neoplastic disease which have occurred among their employees during the period covered by their immediately available files.

It would be expected that the details of the clinical records would be augmented, supplemented and/or verified, insofar as possible, by the various Medical Departments

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through their relationships with their subordinate offices, private physicians, hospitals, clinics and laboratories.

To determine the degree of possible exposure to various potential carcinogens, the various Medical Departments would be expected to request that their Personnel Departments furnish, insofar as their records permit, a detailed employment history, including not only information regarding the employment of the patient in the company or industry, but also any other employment in other industries as covered by their records.

(See Appendix, Pages 2, 3, 4, 5 and 6 for the details of the information to be requested on (1) the initial report, (2) the clinical record and (3) the employment history.)

The Survey Group of the University of Cincinnati would be expected to set up the necessary clerical mechanism to receive the initial reports, to process the clinical records and employment histories and to provide interim and final summations to the Medical Advisory Committee. The tabulations and analyses would be arranged to protect the identity of the companies and/or the individual patients involved in the study through the use of a code system.

2. Objectives

The serious defect in this plan arises from the great variation in the amount and type of information available in files of the various Medical and Personnel Departments. For some companies, the need to collect this data is an entirely new concept. In others, even the provision of medical care programs for the employees is a relatively recent activity.

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This approach, even with optimum conditions, information and cooperation, can only furnish a crude estimate of the prevalence of Neoplastic disease among employees of the cooperating companies who have had exposures to the older conditions and processes. The tabulations cannot be used to ascertain the potential hazards of the newer processes.

However, if a consistent pattern in the occupational histories of this group of cases was found, the presence of overlooked hazards in the older methods might be indicated. Furthermore, if an unusual distribution is reported with regard to type and site of tumor, further epidemiological studies of Neoplastic disease in employees of the Petroleum Industry might be limited to only certain types and sites.

3. Approximate Period of Study

It is readily apparent that, due to the many diverse situations found in the industry, the variation in the degree of cooperation offered by the different companies, the time needed to secure general acceptance of a standardized report and the necessary lag that will be encountered in setting up the clerical mechanism at the University of Cincinnati, this approach will require approximately two years to complete. It would be expected that the final report including cases as they have occurred up to and including January 1, 1951 could not be submitted before 1952.

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II. Current Registry

1. Description

This approach envisions the establishment of a continuing Central Registry for Neoplastic diseases to be employed by the various cooperating companies to report routinely through their Medical Departments proved or suspected cases of Neoplastic diseases which occur among their employees, regardless of site, type of tumor, degree of exposure to various carcinogenic hazards and employment status.

The Medical Departments, under this plan, within the limits of their legal responsibilities, would be expected to report currently to the Survey Group at the University of Cincinnati all cases of proved or suspected Neoplastic disease which occur among their employees.

It would be expected that, in addition to this notification, insofar as possible, a detailed clinical record would be completed by the various Medical Departments, augmented, supplemented and/or verified through their regular contacts with their subordinate offices, private physicians, hospitals, clinics and laboratories.

Furthermore, in order to ascertain the degree of possible exposure of the reported cases to various carcinogenic hazards, processes or environment in or out of the Petroleum Industry, the various Medical Departments would be expected to request that their Personnel Departments furnish, insofar as their records permit, a detailed history, including not only a

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description of the job of the individual in the company and/or industry, but also all other employment covered by their records. It is hoped that this record can be augmented or supplemented, if necessary, by the Medical Departments, since, in many instances, the patient will be in direct contact with the Medical Director or his immediate subordinates.

(See Appendix, Pages 2, 3, 4, 5 and 6 for the details of the information to be requested on (1) the initial report, (2) the clinical record and (3) the employment history.)

It would be expected that the various Medical Departments, either directly or by securing the assistance of their Personnel Department, would furnish, periodically, similar employment histories for certain groups of employees in their company. The groups or samples required for this phase of the study would be selected with a direct request from the Survey Group, but only after personal consultation with the various Medical Directors and subject to the general approval of the Medical Advisory Committee.

(See Appendix, Pages 5 and 6 for the employment history as used for cases which would be sought not for all, but only a sample of the total number of employees in the company or industry.)

The Survey Group of the University of Cincinnati would be expected to set up the necessary clerical mechanism to receive the initial reports, to process the clinical records and employment histories and to provide periodic interim summations to the Medical Advisory Committee. The tabulations

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and analyses would be so arranged that the identity of the companies and/or the individual patients involved would again be protected through the use of a code system.

In the attempt to calculate incidence rates for at least a fraction of the industry, it would be expected that the Survey Group would prepare the plan, subject to the approval of the Medical Advisory Committee, for selecting the needed employee groups for the population studies as previously described.

As an adjunct to the Central Registry, it would seem desirable to create a Central Pathology Service at the University of Cincinnati to whom the various cooperating Medical Departments could forward slides and/or tissues for diagnosis and a uniform classification. This particular activity would stimulate the cooperation of the physicians in the search and reporting of cases to the Central Registry. It would also establish a uniform level for acceptance of a case as one of proved Neoplastic disease. How this service can be established and financed still remains an open question.

2. Objectives

This approach would furnish, in contrast to the prevalence rates of the Retrospective Study, an approximate estimate of the incidence of Neoplastic disease among employees of the cooperating companies, since it is hoped that, for at least a portion of the industry, adequate estimates of the number of employees involved and possible exposures to various potentially carcinogenic hazards will be obtained.

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It would be expected that this plan would augment, supplement and finally supplant the Historical Approach in defining far more accurately the hazard of the older processes. If successful, and since this will be a current registry providing for reports in the years to come, the analyses could be used to ascertain the hazards of the newer processes, provided that the study is maintained and supported for a sufficient period of time to take into account the long latent period commonly found with Neoplastic disease.

It is also possible that this plan, in the future, will provide comparisons of incidence rates not only between various processes, but also geographic areas, racial groups, companies, other industries and the general population.

3. Approximate Period of Study

It would be well to call attention at this point to the fact that the greatest obstacle to this approach is the dynamic almost fluid state of the technology of the Petroleum Industry. This situation will seriously interfere with any logical attempt to define accurately the degree and period of exposure, except in the very broadest of terms. It will be, likewise, the most dangerous factor in the estimation of exposed populations, since process changes bring about the frequent shifting of the employees in the refinery operations.

Also, since it is generally accepted that Neoplastic reactions require usually a relatively long and heavy exposure to even proved carcinogenic agents, and that there is, likewise, usually a very long period between exposure and

reaction, it is readily apparent that the registry must be continued and adequately maintained for a considerable period of time before it will even begin to measure the hazard of the newer processes. It is to be hoped, however, that satisfactory rates measuring the hazards of the older processes would be available much earlier.

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B. It is proposed to continue the exploration and the possible implementation, as soon and insofar as possible and/or feasible, with due consideration and understanding of the wide variation in company policies, medical care programs, management interest and labor relations, of the third and fourth approaches, namely, (III) Employee Health Benefit Plan Study and (IV) the Field Survey for Retrograde or Hyperkeratotic Lesions.

The description, objectives and approximate period of study for both of these attractive and possibly feasible approaches must await further consultation, discussion and pilot trials before they can be brought to the Subcommittee and/or Medical Advisory Committee for their consideration. It is hoped that these two avenues can be explored sufficiently during the summer of 1950 to permit firm planning at the November meeting.

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C. It is proposed to implement, as soon and insofar as possible and/or feasible, with due consideration and understanding of the wide variation in company policies, medical care programs, management interest and labor relations, the last two approaches, namely, (V) Repetition of the Slack Wax Studies and (VI) the Consultation Service.

It is not proposed that the Survey Group take an active part in the Slack Wax Studies, but that the observations will be repeated by individual companies. It is hoped that the Survey Group of the University of Cincinnati, through personal contact, can make certain that adequate observations are secured so this question can be thoroughly explored and evaluated. In serving as an agency to insure that the individual company protocols are valid, acceptable and comparable, it is expected that they can act as a medium of dissemination so that the various other cooperating Medical Departments will have access to this information.

It is planned, likewise, that the Survey Group of the University of Cincinnati will stand ready to assist, upon the specific request of any Medical Department, in the planning of other studies to determine particular and/or unusual hazards. It is not expected that the information so gathered would be disseminated generally unless the interested company permitted this action. The sole objective for this approach would be to insure comparability of studies and observations in case general dissemination or comparisons became desirable.

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A P P E N D I X

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C O P Y

December 20, 1949

Dr. McIver Woody
ESSO Standard Oil Co.
BUILDING

Dear Doctor Woody:

You have told me the plan is being developed to accumulate in the hands of investigators of the University of Cincinnati, who have been designated for the purpose, data with respect to operatives engaged in petroleum refining and petroleum handling who may have been determined to be suffering from or who may be suspected of suffering from cancer which may be attributed to their occupation or to contact with petroleum products. You have asked me if I see any objection from a legal standpoint to transmitting to the designated authorities at the University of Cincinnati the records of such patients.

There has grown up a feeling, and perhaps a right, on the part of patients to have their consultations with their physicians and the physicians' records with respect to the patients treated as confidential between the physician and the patient. Even if the patient's right to have such communications and records treated as confidential is not fully established, I think our anxiety to develop cordial relations between our employees and company doctors ought to compel us to regard those communications and records as confidential. Starting from this premise, I think it is entirely proper from a legal standpoint, and feasible from the standpoint of the relations we want to preserve with our employees, for you to report cases of the kind herein mentioned, provided you keep the identity of the patient strictly confidential. I suggest that these reports may be made under a series of code numbers or under fictitious names, you preserving in your confidential files the identity of the code number or fictitious name of the patient involved. I think if this anonymous scheme is observed in making the reports you have described to me, it cannot offend the patient's legal rights. I feel equally strong it is not likely to cause any disturbance in the relationship between our employees and our company doctors.

I would think that if the designated authorities at the University of Cincinnati desire to compile and use generally in the industry or with the public any statistics with respect to data of the kind herein described, which they receive from our company and from other companies, they ought to again use code numbers so that the identity of the company whose employees are embraced in the statistics will be carefully concealed.

If the foregoing restrictions are observed, I think the confidential nature of the physician-patient relationship will be preserved, and, similarly, the confidential nature of the company records will be preserved and I do not anticipate any trouble would be involved.

Very truly yours,

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ESH A

Original Signed E. S. Hall

Preliminary Notification

I. Identification Data

A. Code Number - All identifying data (Name-Address) to be retained by the Medical Director, correlated with the code number.

B. Age (Year born)

C. Sex

D. Race

II. Clinical Data

A. Type of Tumor

B. Site of Tumor

C. Date of Diagnosis

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Detailed Clinical Record

(To be completed in duplicate)
(One copy to be retained by the Medical Director)

I. Identification Data

A. Code Number - All identifying data (Name-Address) to be retained in the office of the Medical Director.

B. Age (Year born)

C. Sex

D. Race

E. Marital Status

F. Employment Status

II. Clinical Data

A. Dates

1. First Symptom
2. First Visit to Physician
3. First Diagnosis
4. First Treatment or Hospitalization
5. Death

B. Clinical and Pathologic Diagnosis - List of tumors to be reported which will be placed on the reverse of record. This list is not exhaustive but comprises the great majority of terms usually used. When there is doubt concerning the malignant nature of a tumor, it should be reported.

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Carcinoma
Sarcoma
Epithelioma
Endothelioma
} and any term of which one of these words is a part.

Acanthoma
Astrocytoma
Brain Tumors
Chorioma
Chloroma
Cholesteatoma
Embryoma
Ependymoma
Ganglioneuroma
Glioma
Granulosa Cell Tumor (Ovary)
Hypernephroma
Hodgkin's Disease
Leukemia
Lymphoma
Lymphosarcoma
Linitis Plastica (Stomach)
Melanoma
Meningioma
Myeloma
Medulloblastoma
Mesothelioma
Mixed Tumor
Neurocytoma
Oligodendroglioma
Pinealoma
Syncytioma
Seminoma
Sympathoblastoma
Spongioblastoma
Teratoma
Thymoma
Paget's Disease (Breast)
Wilms' Tumor (Kidney)
Ewing's Tumor (Bone)
Grawitz' Tumor (Kidney)

C. Primary Site and Stage

D. Treatment Advised and Received

E. Complications - Metastatic Sites

III. Unusual Exposure to Possible Carcinogens - Including estimates of Degree, Type and Length of Time (As elicited by the Physician) List which will be placed on the reverse of the record.

A. Physical Agents

1. Trauma
2. Radiant Heat
3. Solar Rays
4. Ultraviolet Rays
5. Radioactive Substances or Roentgen Rays

B. Inorganic Substances

1. Arsenic
2. Chromates

C. Organic Substances

1. Aromatic Amines
2. Tar or Pitch
3. Soot
4. Creosote and Anthracene Oils

Detailed Occupational Record

(To be completed in triplicate)

(One copy to be retained by the Medical Director and Personnel Department)

I. Identification Data

A. Code Number

B. Age at Commencing Work

C. Employment Status

II. Occupations and Detailed Employment Record - Listed in Chronological Order

A. Name of Companies and/or Plants

B. Products Handled by Worker

C. Job Descriptions - The Broad Classifications which will be placed on reverse of card.

1. Production

a. Riggers and Drillers
b. Others

2. Refining

a. Cracking
(1) Catalytic
(2) Thermal
(3) Others

b. Lubricant and Paraffin
(1) Crude Wax
(2) Others

c. Straight Run Distillation and Light Ends

d. Special Products

e. Maintenance
(1) Pipe fitters and Boilermakers
(2) Others

f. Control Laboratory

g. Others

3. Transportation
a. Pipe Line
b. Fuel Oil Carriers
c. Others

4. Marketing and Executive
a. Service Station
b. Others

5. Others - Specify in detail

D. Periods Employed

III. Unusual Exposure to Possible Irritants - Including estimates of Degree, Type and Length of Time (As elicited by the Employment Record)

(See list - Detailed Clinical Record)

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