

United States Beryllium Case Registry (1.9524966)

Review of Its Methods and Utility

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AN EPIDEMIC of worker illness, recognized as job-related, occurred in United States beryllium-using industries during the years 1943-1947. In the 20 years since, records of 760 cases of disease associated with all beryllium-using operations, except beryl mining, have been collected in a central file. Located in the Massachusetts Institute of Technology, and supported by the U. S. Atomic Energy Commission, the Beryllium Case Registry, as this project has been named, was established in 1951.¹ Reasons for continuing the Registry are, among others, the fact that interest in the use of beryllium continues to increase, and, because of this, knowledge of disease in the beryllium industry becomes of world-wide importance. Since beryllium poisoning may be mistaken for, among other diseases, tuberculosis, sarcoidosis, and metastatic malignancy, help with accurate diagnosis is an important second value of the Registry. In addition, because of the fact that beryllium has been shown to produce neoplasia in rats, rabbits, and monkeys, study of cause of death in Registry cases will in time establish whether beryllium is also carcinogenic to humans. This communication will discuss the methods the Registry uses, with comments on the limitations and advantages of such a central file in the study of a newly recognized industrial disease.

There are problems associated with the study

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of any industrial disease that do not plague those studying causes of outbreaks of most diseases of public health importance.² For example, trade secrecy is considered an important part of a free-enterprise system of economics. In the case of beryllium disease, there were 3 companies manufacturing fluorescent lighting parts when the workers' illness was first recognized. Because the exact composition of phosphors in use was a jealously guarded secret, it was difficult to be certain of the dose of beryllium that was causing the poisoning. In addition, financial problems associated with launching a new operation are great, and recognition of job-related disease leading to compensation claims is a consequence that hinders accurate study of industrial disease.

In spite of such difficulties, the Beryllium Case Registry has achieved some success. At the outset in 1951 a series of questions that such a collection of data might eventually answer was prepared. There were 8 main questions in the original statement and 5 of these have been reasonably well answered. The questions are:

1. What are the criteria for the diagnosis of beryllium poisoning in both its acute and chronic form?
2. What was the quality of work exposure in cases of beryllium poisoning?
3. What was the quantity of beryllium compounds causing disease?
4. How effective have the controls introduced in 1949 proved to be?
5. What is the clinical course of beryllium disease, its prognosis, and its complications?
6. What has been the response to steroid therapy introduced in 1949?
7. How many workers and neighbors were exposed to similar risks and did not get ill?

ulcerative colitis and Crohn's disease when measured by a turbidimetric method, and we observed no differences between the two diseases. The normal lactoferrin levels suggest that the observed elevation of lysozyme is probably a function of monocyte rather than neutrophil activation.

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Note: Unless sonic really important developments occur, this issue of lysozyme in Crohn's disease and ulcerative colitis is hereby concluded — at least in this Correspondence.—ED.

CORRECTION ON THE NUMBER OF PRESUMED BERYLLIUM-INDUCED OSTEOSARCOMAS IN HUMAN BEINGS

To the Editor: In 1954, autopsy on a beryllium worker revealed an osteosarcoma, finally diagnosed as a chondromyxosarcoma of the right ilium with extensive bilateral pulmonary metastases. In a 50-g sample of this ilium, which included areas of the chondromyxosarcoma, 0.114 µg per gram of beryllium was found. This quantity is only slightly elevated above the background level found in the tissues of urban dwellers, thought to be due to the burning of certain fossil fuels. No other organ or tissue from the autopsy of the worker (reviewed by three pathologists) contained lesions presently considered correlated with harmful beryllium exposure. No beryllium was found in 50 g of the patient's lung.

No other cases of bone sarcoma associated with beryllium workers had been reported in the period ending July 1, 1976. However, by some error, the Beryllium Case Registry has carried this single case as three cases since 1966.^{1,2} To correct the record, I wish to reaffirm that only one case of bone sarcoma in a beryllium worker has been submitted to the Registry.

In 1952 a registry of cases with the diagnosis of beryllium disease was established at the Massachusetts General Hospital³ with funds supplied by the Atomic Energy Commission, and in the past four years by the National Institutes of Health. Reports on Registry findings have been issued from time to time both to solicit cases^{4,5} and to describe this industrial disease,^{6,7} first reported in the 1930's in Europe and the United States in the early 1940's,^{8,9} which continues to be present.

Studies of beryllium in laboratory animals have produced a wide spectrum of pathologic effects.¹⁰ Because of the pressure to decrease the so-called safe level of beryllium, I believe the error in the Beryllium Case Registry warrants publicizing.

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DATA BANKS FOR STANDARDIZED ASSESSMENTS OF COMA

To the Editor: Many of the advantages of a computer-based data bank of clinical cases, described by Dr. tries in the June 17 issue of the *Journal*, have already become evident in an international study of coma in which we are engaged. Standardized methods of assessing initial severity and major complications have been evolved, and a scale devised for evaluating outcome. These procedures have proved practical and consistently reliable when used in two centers in each of three countries (United Kingdom, United States and the Netherlands); they have been applied to coma due to severe head injury¹ and to medical coma.² From the head-injury study it is already clear that the initial clinical characteristics, complication rate and outcome are strikingly similar in these three countries, even though the arrangements for management and the details of clinical care differ considerably. By comparison of a new patient with the existing data base using Bayesian statistics the probability of different outcomes can be calculated.

These two studies are still proceeding, and when they are concluded next summer, there are expected to be prospective data on the computer relating to about 1000 head injuries and 500 cases of nontraumatic coma. It is not as yet apparent how to make these data more generally available. In evolving our system we have taken care to use only features that could be consistently observed by a range of different persons. However, if others were to use this data base, particularly for predictive purposes and therefore as a basis for clinical decision making, it would be important to ensure that the clinical signs elicited from their new patients were obtained in a sufficiently standardized way to be certain that comparison with the established data base was valid. Provided this end were achieved, other users might add to the data base, and updating would be possible at intervals, as sizable numbers of additional patients accumulated.

We are particularly hopeful that this method may make it possible to undertake trials of new therapeutic regimens more expeditiously than by traditional methods. The outcome in patients so treated could be compared with that predicted from the data bank. This process would avoid the ethical problems of a "no-treatment" group, which is always difficult when one is dealing with conditions associated with a high mortality.

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TISSUE BANKING AND TRANSPLANTATION

To the Editor: The concept of preserved bone-allograft reconstruction after tumor resection is of great practical (physical, social and psychologic) importance, especially in the light of encouragement generated by newer chemotherapeutic protocols. Dr. Mankin (*N Engl J Med* 294:1247-1255, 1976) has carried currently available methodology to an exciting point but has warned that this initial enthusiasm must be tempered by respect for the technical difficulties, the unavailable long-term results, and an immense list of unknown factors related to allograft function and biology, including the host's immune response.

The United States Navy Tissue Bank has been concerned with clinical and basic-science research related to technologic development and the clinical efficacy of preserved allografts for over 25

8. As in animal studies, do workers with and without diagnosable beryllium disease suffer a significant increase in malignancy, especially of the bone or lung?

The Registry contains 760 records to date, and this total is constantly increasing. The criteria for inclusion have been kept very simple. They are: first, the establishment of significant beryllium exposure, and second, objective evidence of lower respiratory tract disease. Significant beryllium exposure rests either on epidemiologic evidence, as, for example, a history of work in a fluorescent-lamp manufacturing plant where a series of recognized cases occurred; or on the finding of beryllium by chemical means in tissue or urine. Lower-respiratory-tract disease has been considered present if chest X-ray changes or abnormal physical findings are recorded. Symptoms alone have not been held acceptable unless lung-function abnormalities or X-ray changes are also present.

There are 3 important deficiencies in the Registry: (1) lack of knowledge of the size of populations at risk; (2) incomplete data describing the amount of beryllium exposure; and (3) failure to learn of all cases of the disease in a beryllium-using industry. Because of our experience, and knowing of the increase in the use of beryllium, we urge whenever possible the prospective study of beryllium workers in order to overcome these deficiencies. This would also be urged for any newly recognized hazard.

In spite of these problems, useful knowledge has been derived from Registry data (Table 1). An example is the fact that acute beryllium disease is followed by chronic illness with and without further exposure in 6.2% of all cases (33% in a small series), which leads to the conclusion that those who have suffered acute beryllium poisoning should be removed from beryllium-using work. Registry data show that intensity of exposure, although measured in a

crude fashion, does suggest a dose-disease relationship (Table 2). Delay-in-onset figures show several points of interest. Nearly half of those workers who developed chronic beryllium disease did so at work, probably because of intense uncontrolled exposure. Further Registry data suggest that the longer the delay, now in a few cases more than 15 years, the milder the disease, reflected in increased length of life from date of diagnosis⁸ (Table 3). The decrease in the number of cases diagnosed in the years since industrial hygiene controls were introduced is impressive and is further evidence that the majority of cases are dose-related (Fig. 1).

Mortality of Registry cases is 27.5% (Table 1). Breakdown of mortality by industry, and occurring in worker or neighbor, implies marked differences in exposure. Chronic disease in workers results in 35% mortality, in neighbors 52% (Table 4). Difference from over-all Registry mortality is explained by the inclusion of 215 acute cases, which, because they were more quickly recognized, led to cessation of beryllium exposure. Data collected on 60 neighborhood cases show that contaminated work clothing, rather than distance, was the chief source of exposure (Table 5). In characterizing the disease, Registry data show that beryllium poisoning usually presents as pulmonary disease but pathologic changes may be found in liver, spleen, and kidney tissue, as well as in striated muscle and heart muscle. Recorded abnormalities in calcium metabolism

TABLE 1. BERYLLIUM REGISTRY DATA AS OF
JUNE 1966

	No.	%
Registry records	760	100.0
Acute cases	215	28.8
Chronic cases	498	67.0
Acute to chronic cases	47	6.2
Total dead	210	27.5
New cases (1965-66)	19	—
Deaths (1965-66)	9	—

TABLE 2. INTENSITY OF EXPOSURE IN FATAL CASES
(BERYLLIUM REGISTRY DATA, 1965)

Exposure distance	No. of cases	Intensity
Outside & over ½ mile	1	1+
Outside & less than ½ mile	6	2+
Under same roof	15	3+
In handling & breathing zone	153	4+
No data	8	—

Adapted from Hardy, H. L.⁸

TABLE 3. DELAY IN ONSET—CHRONIC DISEASE

Time	No. of cases
< 1 month	126
1 month-1 year	27
1-5 years	89
5-10 years	56
> 10 years	12

Adapted from Hardy, H. L.⁸

and serum-protein pattern support the view that this is a systemic intoxication, not a local lung disease. There is no Registry evidence as yet that beryllium causes cancer in humans. And, in contrast to Boeck's sarcoidosis, there are few (only 10) cases of tuberculosis as a complication in 760 cases of the industrial disease. Study of intercurrent events in the medical history of individuals with chronic disease who are now dead shows that these events may have been precipitating factors leading to clinical illness due to mobilization of stored beryllium, explaining the apparent delay in onset.

What we have described thus far was taken from the data collected over the years, using Keysort cards originally intended for a maximum of 300 cases. For several years past the Keysort system has proved of little value. Constant introduction of newly recognized cases, addition of clinical observations of a single case through the years, and assessment of response to treatment are examples of needs that are not met by the Keysort card-punching system.

In July 1965, an effort was begun to use the Massachusetts Institute of Technology computer. The access and retrievability afforded by computers to information encoded for their use is an enormous aid to anyone wishing to do research on a file such as the Beryllium Case Registry. Of equal importance, however, is the discipline imposed on the individuals responsible for putting the information into the registry. The coding must be well planned, consistent, and thorough in order to allow computer access.

The computer is not able to interpret as a human being is prone to do. We have, therefore, recoded all the information in the Registry onto new sheets. These codes have been carefully thought out and the information throughout the Registry has been made as uniform as possible.

To retrieve the information, we have developed 2 general classes of computer programs. The first allows the researcher to search for cases that meet a set of criteria he has established and then print out the relevant variables he has specified. For instance, the researcher may ask the machine to print out the delay in onset and duration of disease for all workers from a particular industry who were above a certain age when the disease was contracted and for whom autopsy material is available. In addition to the "search" program we have developed a contingency or scattergram program that allows the researcher to make a table plotting the frequency distributions of 2 variables against each other. This may be done either for the whole Registry or for a subpopulation. A simple example would be to plot the age on the X axis against sex on the Y axis for all individuals who are still alive.

These programs and the data for the Registry are stored in the time-shared computer at the M.I.T. computation center. Time sharing allows the researcher to ask the computer to perform the above operations by typing instructions on a teletype that is directly connected to the computer. The computer then performs the desired analysis and types the results back to the in-

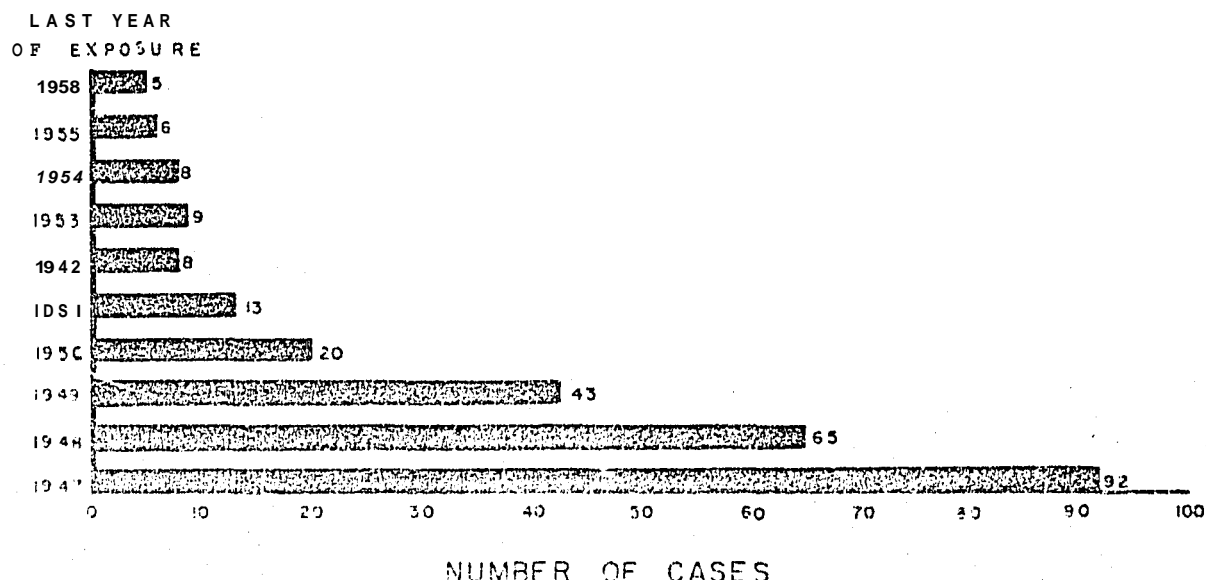


Fig. 1. Effect of control of beryllium hazard, showing impressive decrease in cases in years since introduction of industrial hygiene controls.

TABLE 4. MORTALITY FROM CHRONIC BERYLLIUM DISEASE IN 475 CASES

Industry	Living (No.)	Dead		Total
		No.	%	
Extraction smelting	57	21	27	78
Fluorescent	170	79	32	249
Atomic	33	6	15	39
Neon	8	15	65	23
Ceramics	12	9	43	21
Foundry machining	12	9	43	21
Cathode	11	8	42	19
Alloy	3	10	77	13
Tube disposal	2	7	78	9
Other	3	—	—	3
TOTAL	311	164	35	475*

*An additional 60 cases are reported on the basis of "neighborhood" exposure; of these, 29 individuals are living and 31 (52%) are now dead (see Table 5).

TABLE 5. NONOCCUPATIONAL (NEIGHBORHOOD) CASES

Source of contact	No. cases
Clothes alone	27
Air alone	18
Clothes plus air	13
No data	2
TOTAL	60

investigator on the teletype. These analyses usually require 2-5 sec. to complete, and in essence the researcher has immediate access to any of the information stored in the Registry. He, therefore, can ask new questions based on the results of the analysis just performed, allowing him to test hypotheses and pursue avenues of thought that otherwise would take weeks or months or, perhaps, would not be done at all.

Our future plans call for the expansion of our data base to the whole Registry. (All the coding has been done, but we must now check the reliability and consistency of the data.) In addition, we will implement statistical programs that will allow more analytic procedures to be performed in addition to the descriptive procedures already available and described above.

In June 1966, a modest but practical test of the use of Registry data in the computer was made by assessing the value of steroids as therapy in chronic beryllium disease. We took the case records of 50 patients treated with steroids for 5 consecutive years and 50 managed without steroid therapy. Each of these chosen 100

TABLE 6. MORTALITY FROM CHRONIC BERYLLIUM DISEASE IN 100 STUDIED CASES, BY INDUSTRY

Industry	Treated (No.)		Untreated (No.)	
	Dead	Living	Dead	Living
Extraction smelting	1	9	6	7
Fluorescent (high & low phosphor)	5	18	12	9
Ceramics	—	—	—	2
Alloy	—	3	2	—
Atomic	—	9	3	7
Cathode	—	1	1	—
TOTAL	6	40*	24†	25

*Excludes 4 "neighborhood."

†Excludes 1 "neighborhood."

TABLE 7. LENGTH OF ILLNESS IN 100 STUDIED CASES

Patient survival	Duration of illness (years)					
	1+ to 3	3+ to 5	5+ to 10	10+ to 15	15+ to 20	20+
TREATED						
Living	—	—	9	16	12	1
Dead	—	—	—	2	1	—
TOTAL	—	—	9	18	13	1
UNTREATED						
Living	3	1	—	5	7	5
Dead	9	8	6	1	1	—
TOTAL	12	9	6	6	8	5

TABLE 8. DURATION OF TREATMENT IN 50 STUDIED CASES

Patient survival	Duration of treatment (years)			
	5-7	8-10	11-13	14-16
Living	14	11	14	5
Dead	1	—	4	1
TOTAL	15	11	18	6

TABLE 9. COMPLICATIONS OF DISEASE IN 100 STUDIED CASES

Patient survival	Complication (No. of patients)				
	Renal	Heart	Pneumo-thorax	Cancer	Resp. infect.
TREATED					
Living	9	11	2	1	2
Dead	—	5	2	—	—
UNTREATED					
Living	3	2	—	1	1
Dead	3	13	3	1	1

TABLE 10. LENGTH OF ILLNESS IN 409 CHRONIC CASES

Duration illness (years)	Treated (No. patients)			Untreated (No. patients)			Total
	Living	Dead	Total	Living	Dead	Total	
- 1	—	4	4	—	18	18	22
1+ to 3	8	4	12	4	33	37	49
3+ to 5	11	8	19	5	21	26	45
5+ to 10	29	31	60	12	9	21	81
10+ to 15	67	23	90	21	3	24	114
15+ to 20	47	15	62	16	—	16	78
20+	9	3	12	7	1	8	20

cases was well studied with recent knowledge of the patient's clinical status. The indices chosen for study were mortality, length of illness, and complications (both of the disease and of the treatment). Unknowns that may be important are the severity of disease when steroid administration was begun and the precise course of therapy. Table 6, which lists the cases by industry, shows that of the 50 treated patients, 44 are alive, and of those untreated, half are dead. Length-of-illness data from the computer show greater chance for survival in the treated series (Tables 7 and 8). Complications of the disease are shown in Table 9. Cor pulmonale stands out as the fatal complication. Complications of therapy have been surprisingly few and in only 2 instances, to our knowledge, have

they led to cessation of the use of steroids. These complications have consisted of frequent infections (2 cases), skin changes (4 cases), hypertension (1 case), weight gain (4 cases), "diabetes" (2 cases), "psychosis" (3 cases), ulcer (1 case), "moon face" and "others" (3 cases).

Because of the novelty of computer use, a check was made by the time-consuming task of studying all Registry records of chronic disease (535). The same indices of mortality, length of illness, and complications of disease and of steroid therapy were studied. Tables 10 and 11 show the greater length of illness-survival time for the treated patients. Of the 67% receiving steroids, 59% were reported improved. The length of illness shown in detail further supports the conclusion that steroid therapy is of value in treatment of chronic beryllium poisoning. The data on complications of disease are similar in character to computer-derived data (Table 12). As in the smaller group, there was a minimal number of complications attributed to steroid therapy among the 277 patients so treated. They consisted of peptic ulcer (3 cases), osteoporosis (6 cases), "diabetes" (6 cases), "psychosis" (9 cases), hypertension (7 cases), and frequent infections (4 cases).

It is of importance and interest that the small computer study of 100 cases gave results similar to those discovered by the more time-consuming method of studying Registry records and Keysort cards, and allows the following conclusions:

1. There is significantly lower mortality and an increased survival time in steroid-treated patients with chronic beryllium poisoning.
2. The recorded complications of steroid therapy do not constitute enough of a risk to withhold a drug that reduces mortality and prolongs life.

In summary, while there are a number of serious weaknesses in the United States registry of

TABLE 11. DURATION OF TREATMENT IN 250 CHRONIC CASES

Patient survival	Duration of treatment					Intermittent
	Years					
	1 or less	1+ to 3	3+ to 5	5+ to 10	10+	
Living	22	27	19	48	44	16
Dead	26	14	9	9	10	6
TOTAL	48	41	28	57	54	22

TABLE 12. COMPLICATIONS OF DISEASE IN 535 CASES

	Complication (No. of pt.)					
	Cancer*	Renal	Heart	Pneumonia-thorax	TB	Calculi†
Treated	7	35	68	27	—	5
Untreated	7	19	47	16	7	—

*Among the treated patients there was 1 case each of cancer of the cervix, skin, lung, CNS, rectum, breast, and eye; among the untreated patients there were 3 cases of cancer of bone, 2 of lung, 1 of colon, and 1 of nasopharynx.

†Two instances of gallstones, 2 of lung stones, and 1 of salivary calculi.

industrially related beryllium disease, this project is proving valuable. Chief weaknesses are lack of knowledge of total numbers of people exposed and ignorance (with few exceptions) of the quantity of beryllium compounds inhaled.

A Keysort card system has proved of little value in utilizing data, since the Registry exceeded 300 cases, although the work sheets used to record information received continue to serve as reference point. Presently the help of the M.I.T. computer is under study in order to make more versatile and dependable use of the data in the 760 records. There are learning problems for those of us who do not know computer technology. Fortunately, a number of bright young men and women find the use of the computer rewarding and understandable. Our brief experience suggests that the computer will prove of great value in utilizing the Registry. We are currently using computer techniques to study correlations that may exist between lung-function studies and pathologic changes on the one hand and clinical course, work exposure, prognosis, and therapy on the other. Such studies are intended to help make accurate diagnosis, increase knowledge of the

course of beryllium disease, and aid the physician in treating patients.

The use of beryllium and its compounds is increasing; the hazard of certain levels of exposure to respirable beryllium compounds is definitely established. There is good evidence that the risk can be controlled by conventional industrial hygiene methods. Retrospective and ongoing studies of a central file of workers ill with a newly recognized job-related disease, as exemplified by the United States Beryllium Case Registry, in spite of its deficiencies, has given and is giving, with computer help, useful knowledge of the disease, its medical management, and its control.

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ERRATUM

The article, "A Two-Year Study of Myocardial Infarction in Industry" by Thomas E. Cardillo, M.D. (*J Occup Med* 9:175, 1967) contains an error.

Sentence 9 of the fourth paragraph on page 177 under *Results* should read, "It seems obvious that the oil companies have greater numbers in the younger age groups or that we have an older population."