Evaluation in Laboratory Practice

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EVALUATION as a laboratory tool is basically a means of communication. It is used to compare test efficiency against a standard (patient groups of diseases and conditions) and as a means of conveying information between technologists within a laboratory and also between laboratories. Evaluation studies have been conducted and their results have been transmitted locally, regionally, nationally, and internationally.

Three other points about evaluations in laboratory practice should be remembered:

- Evaluation studies are a necessary and effective means of gathering information.
- They are a means rather than an end and as such are, or at least should be, part of a more broadly defined endeavor.
- Evaluations should be properly designed to reach the desired objectives.

Evaluation studies of serologic tests for syphilis have been conducted in the United States by the Public Health Service since 1935. The first Public Health Service evaluation study (*1*) was made to determine the reliability of several serologic tests for syphilis then in use in this country.

All authors of tests or those who had modified preexisting procedures were invited to participate. When a test-author had originated two procedures, one test was performed by his designee in a laboratory in a different city. More than 1,200 blood and spinal fluid specimens were distributed to the participants. The donors included patients in several stages of syphilis infection and presumably nonsyphilitic persons with and without other diseases or specified conditions. Results were evaluated as to specificity and sensitivity in each of the several disease categories.

This study was considered successful since (*a*) it allowed all testing to be performed by the test-author under nearly ideal conditions, (*b*) the relative efficiencies of several tests authored in this country were determined for the first time, and (*c*) data acquired indicated that the most efficient flocculation-type tests were as efficient as complement fixation tests for testing either blood or spinal fluid.

Some tests did not fare well in this study and many are no longer used. Test names such as Brem, Johns, Lufkin-Rytz, Ruediger, and Williams may not be remembered by many. The report of this study had wide distribution and probably had an effect on tests that were later adopted by laboratories. Thus the study was a contribution as a means of communication and effective in gathering pertinent and needed information in an unbiased manner.

Had these results been all that had been expected of this evaluation study, it would have stopped here. The real objective of the major endeavor in which this study was a small but significant part was to attain and maintain the high level of efficiency in serologic testing in all laboratories in the United States that would be needed to support an effective syphilis control program. Finding that test X did well in the hands of the author did not indicate that it would necessarily be performed with equal efficiency by others. It was therefore necessary to evaluate the performance of these tests in other laboratories.

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The first such attempt on a nationwide scale was started in 1936 and finished in 1937 (*2*). The directors of 39 State, municipal, and private laboratories expressed a desire to participate in this study, and of these, 30 laboratories were selected: 11 State, 5 municipal, and 14 private. Some laboratories performed more than one kind of test, so that 51 performances of 19 separate serodiagnostic methods were available for evaluation.

Approximately 200 blood specimens from syphilitic and 100 from nonsyphilitic donors were distributed in this study. Participating laboratories were not named in the report, but were designated by an arbitrarily chosen number. Laboratory test results were evaluated as to sensitivity and specificity and also compared with the test-author results. The final report of this study contained, among others, the following comments:

"It is quite apparent that the performance of some of the tests in some of the laboratories is inadequate. Obviously, in certain laboratories improvement should be brought about in the performance of well-recognized tests, the value of which has been demonstrated in this study and in the first evaluation project. Likewise, some of the tests should either be modified to increase their sensitivity or specificity or both, or be abandoned.

"The directors of laboratories performing serodiagnostic tests for syphilis should have, and should avail themselves of, the opportunity of comparing their results with those of well-qualified serologists in other laboratories performing the same test on comparable samples from known syphilitic and presumably nonsyphilitic individuals. The committee recommends that such a system of comparative examination of tests be extended annually to all State laboratories. In turn, the State laboratories should offer a similar opportunity to local laboratories."

Arrangements were made for yearly evaluation of serologic tests for syphilis for the State laboratories, but it was evident that the thousands of laboratories and technologists in this country would need to be brought into this program if the quality of testing was to be effective on a nationwide basis. It was also evident that this could not be done through the efforts of the Public Health Service alone. At the end of the 1937 study the committee made the following recommendations:

1. "That provision be made for adequate training of State and local laboratory technicians in the laboratories of the originators of the methods employed in the respective laboratories, and that in the future only thoroughly competent technical personnel be employed.

2. "That a system of periodic inspection of State laboratories by thoroughly trained serologists of the U.S. Public Health Service be inaugurated and made available upon request of State health officers, and that advantage be taken of the system of comparative examination of serodiagnostic tests for syphilis to be extended annually by the U.S. Public Health Service.

3. "That the facilities available for special study of serologic methods in the Venereal Disease Research Laboratory of the U.S. Public Health Service at Stapleton, Staten Island, N.Y., be further utilized for the training of personnel from State laboratories.

4. "That the need is again emphasized for the development by State laboratories of a system of periodic comparative examination of the performance of serodiagnostic tests by municipal, hospital, and private laboratories located within the respective States.

5. "That full advantage be taken of existing local laboratory facilities and that provisions be made to approve and subsidize qualified local laboratories for the performance of diagnostic services in the control of syphilis."

These were the guidelines for the several steps to be taken in the major endeavor aimed at mutual improvement in laboratory procedures. Evaluations were then and still are an important part of this program.

Evaluation studies of serologic tests for syphilis have been conducted yearly to this date, with few exceptions, by the Public Health Service for the State laboratories. This yearly study, which originally provided for distribution of whole blood aliquots, is now conducted by distributing 200 prepared and code-numbered serums to each laboratory.

The relative efficiency of a laboratory performance of test X is determined by weighing reported results against control performance of the same test. Reproducibility within a lab-

oratory, with any given test, is also evident in this study, since 200 code-numbered serums distributed contain many duplicates. The report of this study lists each participating laboratory by name and records the results obtained on each specimen in the control performance of each test. The design of this study has been adjudged adequate to meet its objective (*3*), and it is being used as a pattern for many of the intrastate evaluation studies.

The effectiveness of national serologic evaluation studies was greatly improved as the State laboratories extended this service to the laboratories in their jurisdictions.

Dr. A. V. Hardy, as chairman of the Conference of State and Provincial Public Health Laboratory Directors, conducted a survey to determine the status of intrastate serologic evaluations in 1951. His report (*4*), in 1952, shows that 40 laboratories—36 State, 2 Territorial, and 2 city—had active evaluation programs. More than 4,200 laboratories were participating in the evaluation studies conducted by these 40 laboratories. Twenty-nine of the laboratories had been conducting evaluation studies for 10 or more years at that time with the two earliest, New York and Michigan, beginning in 1906 and 1933, respectively. Hardy's report contained the following statement: "Judging by the appended notes on the questionnaires, the intrastate serology programs are being increasingly recognized as an important educational activity."

The intrastate evaluation studies listed in Dr. Hardy's report had varied designs. Four State laboratories, including New York and Michigan, had been distributing only 10 specimens a year to each laboratory, whereas 16 laboratories were sending more than 100 specimens, and 7 of these were distributing 200 or more specimens. The design of some of these endeavors was then obviously inadequate to serve as an evaluation of testing, but all of them had value in acting as a communication between the State and local laboratory programs and personnel.

In 1935 (*1*), in 1941 (*5*), and again in 1956 (*6*), evaluation studies were conducted by the Public Health Service to determine the relative efficiencies of the serologic tests for syphilis. Donors for these studies included several groups of patients with diseases capable of producing false positive reactions, such as, malaria, pneumonia, leprosy, and infectious mononucleosis, in addition to nonsyphilitic and several syphilitic categories. This approach was necessary since these studies were designed to ascertain the relative effectiveness of each test in identifying syphilis when present and in avoiding false positive reactions not only in normal individuals but also in nonsyphilitic patients having diseases or conditions that might produce false reactions. Each test was performed by the test-author or his designee so maximum efficiency for that procedure could be anticipated.

The Venereal Disease Research Laboratory, in its capacity as a World Health Organization serologic reference center, has included in the yearly evaluation studies the central laboratories of British Guiana, Canada, Ceylon, Curacao, Denmark, El Salvador, Mexico, Peru, Taiwan, Trinidad, Uruguay, and Venezuela. This laboratory is also conducting an evaluation of the fluorescent treponemal antibody test and several modifications with laboratories in England, France, Denmark, Japan, and Italy. These international evaluations are bridges over which information and ideas regarding laboratory operations in several parts of the world flow to the mutual advantage of all participants.

The other extreme is the use of small evaluation studies confined to one laboratory and participated in by the several laboratorians in the serology section. This practice, employed in the Venereal Disease Research Laboratory and in some State laboratories, is useful as a periodic training aid.

Evaluations have a permanent place in laboratory practice. Since the practice of medicine, particularly its public health aspects, is more and more dependent on laboratory findings, and since laboratory work must be continually assayed to insure high quality, evaluation of laboratory practice must be one of the primary mechanisms for ascertaining the need for corrective measures and determining the effects of any taken.

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Services in Public Housing Projects

A joint task force to promote health, education, and social services for tenants of public housing projects was set up in March 1962 by the Department of Health, Education, and Welfare and the Housing and Home Finance Agency. Mrs. Marie McGuire, Commissioner of Public Housing, and Wilbur J. Cohen, Assistant Secretary of the Department of Health, Education, and Welfare, will direct the joint program.

Public housing projects contain half a million dwelling units operated by some 1,200 local housing authorities. The average annual income of families in public housing is $2,373. When a family's income exceeds the local maximum, it has to move out. Forty-seven percent of the families are Negro.

An estimated 450,000 persons living in public housing projects are on relief rolls; 34 percent of all families are receiving social security or assistance checks. Twenty-five percent of all families are one-parent families, mostly fatherless.

The aim of the joint committee is to stimulate development of services needed by families in public housing, including aid to the aged, programs to avert juvenile delinquency, job training, day care facilities, health programs, rehabilitation of the disabled, and programs to promote better management of money and better housekeeping. Specific actions will be recommended to constituent agencies of the Department of Health, Education, and Welfare and the Housing and Home Finance Agency. Some of the recommendations will be concerned with projects to demonstrate what might be done by providing a concentration of services through the housing project offices.

Several bills passed recently by Congress merit the special attention of public housing commissioners trying to provide needed services, according to Assistant Secretary Cohen. Among the legislative actions he mentioned were: authorization granted last year for a demonstration program in juvenile delinquency prevention; authorization for vocational education programs, including training in home economics and practical nursing, and distributive education; authorization of programs of the Office of Vocational Rehabilitation; the Community Health Services and Facilities Act of 1961; and the Manpower Development and Training Act.

First Year's Activity Under Kerr-Mills

A report of the first year of providing medical care through public assistance programs under Public Law 86–778, popularly known as the Kerr-Mills legislation, was prepared by the Department of Health, Education, and Welfare and submitted to the House Ways and Means Committee in March 1962. The report covers activities for the period from October 1, 1960, when the bill became effective, through October 1961.

The Kerr-Mills bill contains two major provisions: substantial increase in Federal funds to States for improvement or development of medical care services in existing old-age assistance programs (OAA) and authorization of a new Federal-State program of medical assistance for the aged (MAA) to serve those who are above the financial level of eligibility of old-age assistance but unable to pay medical costs. The MAA program is the one most frequently identified with the Kerr-Mills bill.

In the first year, 19 States and Puerto Rico and the Virgin Islands had set up MAA programs, according to the report. The States were: Arkansas, Hawaii, Idaho, Illinois, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, New Hampshire, New York, North Dakota, Oklahoma, Oregon, South Carolina, Tennessee, Utah, Washington State, and West Virginia. (An appendix to the report showed that, as of January 1962, Alabama, California, Connecticut, Maine, Pennsylvania, Vermont, and Guam had established MAA programs, making a total of 25 States and 3 other jurisdictions with MAA programs.)

Six States (Arkansas, Hawaii, Massachusetts, North Dakota, Washington, and West Virginia) provided some care in all five major areas: hospitalization, nursing home care, physicians' services, prescribed drugs, and dental care.

All 21 jurisdictions provided for hospitalization, with varying limitations as to the number of days of care, nature of the medical need, or type of care offered. Nursing home care was included in 14 of the State programs. In most instances, no restrictions were imposed except with respect to rates of payment. In four States, however, care was restricted to post-hospital recovery.

All programs except Tennessee's provided physicians' services. In Puerto Rico and South Carolina, such services were available only as outpatient clinic services. In 13 programs, services were limited as to the number of visits during a given period, the nature of the illness, or the scope of care offered.

Prescribed drugs were covered in 12 States; they were available without narrow limitations in 8 of these States. Dental care was included with restrictions in 10 programs. Most of these programs did not provide for dentures.

Of the 21 State plans in operation, 9 provided the same breadth of services as were available in the old-age assistance programs of the same States. Seven States provided for less service, omitting dental care and prescribed drugs or nursing home care. Five States provided for more services in MAA than in OAA programs.

Payments to hospitals, physicians, and others supplying medical services (vendor payments) were being made in October 1961 at an annual rate of $164 million. Expenditures are expected to reach $215 million during fiscal year 1962, the report stated.

In October 1961, there were 66,000 recipients (persons for whom vendor payments were made) in the MAA program. Approximately 30,000 were transferred from old-age assistance rolls, principally in New York and Massachusetts. The distribution of recipients among the States ranged from fewer than 50 in Arkansas, Utah, and the Virgin Islands to 27,920 in New York. More than 90 percent were in five States: New York, Massachusetts, West Virginia, Maryland, and Michigan.

Most States participating in the MAA pro-

gram specified $1,500 or $1,200 as the amount of annual income a single person may have and still receive assistance, although Louisiana permitted an income of $3,000 for persons needing hospitalization. Illinois, Massachusetts, and New York permitted an income of $1,800, while Maryland, South Carolina, and Tennessee used a figure below $1,200. Limits that have been set on personal or real property a person may have are somewhat more liberal than those used in old-age assistance programs, the report pointed out.

The Federal Government participates to the extent of from 50 to 80 percent of the cost of the medical payments in MAA programs, the higher percentages going to the States with the lowest per capita income.

The expansion of medical services made possible by the Kerr-Mills bill in old-age assistance and the other public assistance programs is also described in detail in the report. The number of States making vendor payments under OAA programs increased from 44 to 47 during the year. During September 1960, OAA vendor payments divided by the total number of persons on old-age assistance totaled less than $8.21 per person in half the States and more than that in the other half. In October 1961, the median figure was $11.75, a 43 percent increase. In fiscal year 1961, OAA medical care payments totaled $303,810,000; for fiscal year 1962, the figure is expected to be around $315 million.

The increased Federal participation authorized by the Kerr-Mills bill in OAA medical payments resulted in an increase of $87,703,000 in Federal funds going to 48 States during the year beginning October 1, 1960, over the previous year. The States spent $39,267,000 of this money on additional medical care for the aged, including $12,961,000 for the new MAA program. The remaining $48,436,000 was used to maintain existing services while freeing State funds for expansion or improvement of programs in other federally aided assistance categories. Most of the States that expanded medical services of OAA programs also broadened medical care in the assistance categories for the blind, permanently and totally disabled, and dependent children. The national expenditure for vendor payments provided through all public assistance categories, including MAA, is expected to be about $679 million in fiscal year 1962.

During the period covered by the report, eight States made, or were about to make, vendor payments for the first time for medical care in a public assistance program. In these States, medical care for public assistance recipients had previously either been covered through cash assistance payments on which maximums are usually placed, or provided through whatever free community resources were available.

The report stated that a true evaluation of the States' efforts to provide medical care to the aged through public assistance requires consideration of the OAA and MAA programs simultaneously. This is because the MAA and OAA programs of the various States differ in medical care provisions and in eligibility requirements, so that persons in a particular set of financial and medical circumstances might obtain medical care through MAA in one State and through OAA in another. Moreover, as a person's circumstances and needs change, he may be transferred from one program to the other.

The combined average payment of each of the 16 States reporting expenditures under MAA in October 1961 was higher than the OAA average vendor payment for those States in September 1960. The difference was substantial in most of the States. In the four States (New York, Massachusetts, North Dakota, and Idaho) in which the average OAA vendor payment dropped during the period, the decline was more than offset by new MAA expenditures.

A final factor pointed out in the national picture was that States with high average medical care vendor payments in OAA programs also strongly tend to be the States with low OAA recipient rates. Of the 15 States with average OAA vendor payments above $20 in October 1961, only 1, Washington, had a recipient rate higher than the national average of 134 recipients per 1,000 persons 65 years of age and over in June 1961. At the other extreme, of the 17 States with vendor payment averages of less than $5, all but 4 States had recipient rates above the national average.

Legal Note . . . . Dental Health and Fluoridation

County ordinance requiring fluoridation of county water supply by water company upheld as valid exercise of county council's police power to protect the public health. *Readey* v. *St. Louis County Water Company*, 352 S.W. 2d 622 (Mo. Supreme Court, Dec. 1961).

In upholding the authority of St. Louis County to require fluoridation of water supplied to the county, the Supreme Court of Missouri has joined the courts of last resort of eight other States which have upheld the fluoridation of public water supply as a valid public health measure.

In the Missouri case, a 1959 ordinance of the St. Louis County Council directed the St. Louis Water Co., a corporation which provided a water supply and distribution system for the county, to add sufficient fluoride to the water it supplied to county consumers to maintain a fluoride concentration of 1 part per million gallons of water.

The plaintiffs, Readey and seven other resident taxpayers of the county who used water distributed by the company, brought suit against the water company, the county council, and the acting county health commissioner to enjoin the enforcement of the ordinance, claiming that it violated various provisions of the Federal and Missouri Constitutions.

In the trial court, the action against the water company was dismissed, but an injunction was granted restraining the county council and county officials from enforcing the ordinance on the grounds that it violated provisions of the State and Federal Constitutions. On appeal by the county, the Missouri Supreme Court reversed the trial court and upheld the ordinance.

The plaintiffs contended that: the ordinance violated the 14th amendment to the Constitution of the United States, and article I, section 10 of the Missouri constitution, in that it compelled them to drink fluoridated water against their wills; in violation of the first amendment to the Federal Constitution, the ordinance subjected Christian Scientists to forced medication contrary to their religious beliefs; the county council had no power to enact an ordinance which included municipalities of the county; and finally, the measure violated Missouri statutes relating to the adulteration and misbranding of nonalcoholic drinks.

Protection of Public Health

Turning first to the power of the county to enact the ordinance, the opinion of the court pointed out that under article IV, section 37 of the Missouri constitution, the implementing State legislation, and the charter of St. Louis County, broad powers in the field of public health were granted the county. The opinion concluded that in the exercise of these powers the council was authorized to enact ordinances tending to enhance the health of all residents of St. Louis County, irrespective of whether they also reside within a municipality.

In considering whether the ordinance was a public health measure, the opinion noted that, in effect, water supplied by the water company was the only public water supply available to residents of the county. This water, which is taken from the Missouri River, naturally contains an average of 0.5 part of the fluoride ion per million gallons of water, so that the effect of the ordinance was to require the addition of 0.5 part fluoride per million to achieve the desired level. It was admitted that the addition of fluoride did not improve the water quality, but was for the purpose of affecting the dental health of consumers of water, and that dental caries is not a contagious or communicable disease and cannot produce an epidemic.

While the plaintiffs introduced evidence tending to show adverse effects of fluoridation, the county's evidence tended to support the view that fluoridation in the amount proposed would not have any harmful effects, and would reduce dental decay by as much as 65 percent in children up to 14 years of age, a benefit which they would retain as they matured. The opinion noted that according to the county's evidence, "there is phenomenal agreement among professional and scientific groups in the United States and in the world that fluoridation of public water supplies in the amount provided by the ordinance in question is of great significance in terms of general health, in producing a dental caries resistant enamel on teeth."

In the light of the evidence, it was held that the county council could reasonably have found that fluoridation would effectively and extensively decrease tooth decay, particularly in children, but with benefit to all, and that the ordinance proposed a "safe, practicable, relatively inexpensive, and efficacious public health measure."

Constitutional Challenges

Religious freedom. Since the plaintiffs did not claim to be Christian Scientists, or introduce any evidence showing that fluoridation would infringe the religious beliefs of any group, the court dismissed the claimed violation of the first amendment. The opinion did note, however, that if fluoride in water constitutes medication, and the ingestion of medication violated a religious belief of any county resident, the ordinance did not change the situation since fluoride was naturally present in the water.

Fourteenth amendment. The plaintiffs urged that their freedom to choose whether to drink water containing fluoride was a "liberty" protected by the 14th amendment, subject to regulation by law only as necessary to assure enjoyment of the same freedom by others or "under the pressures of great dangers."

This argument was rejected, the opinion holding that the test of violation of the due process clause of the 14th amendment was not as limited as plaintiffs' position and quoted with approval the test enunciated in *West Coast Hotel Company* v. *Parrish*, 300 U.S. 379, 381: "Liberty under the Constitution is thus necessarily subject to the restraints of due process, and regulation which is reasonable in relation to its subject and is adopted in the interest of the community is due process."

In this light, the reasonably expectable and valuable benefit which the council had determined would accrue to the community as a whole from the ordinance, already found in the court's opinion to bear a reasonable relation to public health, "justifies the resulting infringement of the individual's freedom of choice."

In answer to the argument that the measure would benefit not the whole community but a particular class, that is children up to 14 years of age, the opinion upheld the council's finding of a community benefit and commented that "of course, it is apparent that children become adults."

The judgment of the council that fluoridation of the public water supply was a more effective method than topical application or fluoridation of individual water supplies was also upheld as a reasonable conclusion from the evidence presented.

Misbranding and Adulteration

The allegation that the ordinance would violate a State law prohibiting the adulteration or misbranding of nonalcoholic drinks and providing that a nonalcoholic drink is adulterated when it contains any fluorides or fluorine compounds was summarily rejected by the opinion which held that water was not included within the scope of the statute.

NOTE: Fluoridation has been upheld by the highest court of the State in California, Iowa, Louisiana, Ohio, Oklahoma, Oregon, Washington (two cases), and Wisconsin. It has also been upheld by lower courts in Maryland, Massachusetts, North Dakota, Pennsylvania, and South Carolina. (See "Water Fluoridation and Civil Rights," by James A. Tobey, *Public Works Magazine*, January 1962.)—SIDNEY EDELMAN, *chief, Environmental Health Branch, Public Health Division, Office of the General Counsel, Department of Health, Education, and Welfare.*