THE PUBLIC HEALTH LABORATORY OF THE FUTURE*

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In uncertain times such as these, it is hazardous to predict events even in the near future. To foretell happenings 10 to 20 years hence is even more dangerous. In spite of political changes, however, the human race is certain to require public health services and medical attention, and there is no doubt that public health laboratories will play a great role in providing them.

LABORATORY TESTS CURRENTLY PERFORMED

There is considerable variance in the number and types of laboratory tests performed in health department laboratories. In general, including the activities of the laboratories in the larger States, these may be classified as being in the fields of microbiology including serology, in virology, hematology, and metabolic studies.

The first of these groups embraces tests more commonly performed in health laboratories today. Microbiology, with bacteriology, parasitology, and mycology, is one of the most important of present-day laboratory functions. Numerically, serology is still the leading activity because of the continuing preponderance of serologic tests for syphilis. Virology is an expensive new service that has developed in public health laboratories within the past few years. Hematology, with its morphologic examinations and tests relating to the proper administration of blood banks, is an important field for the future. And no one is now able to foretell the place that metabolic studies, including tests relating to endocrinology and toxicology, will take in the public health laboratory of the future. Indeed, biochemical studies incorporated in multiphase surveys are being done in larger numbers day by day.

Advances in public health practice have eliminated many of the communicable diseases for which extensive public health laboratory work was required in the past. The advent of antibiotics has eliminated the need for extensive bacteriologic study in many cases. This is particularly true in the pneumonias, in gonorrhea, and with certain septicemias where routine blood cultures formerly were done. These advances promise to reduce the need for diagnostic bacteriologic tests to a very few highly standardized and much improved procedures.

The group of viral and rickettsial diseases seems to present an increasing laboratory problem. Unless control methods not now known are developed against this group of diseases, the public health laboratories will be called on more and more to provide diagnostic techniques for their recognition. Because of the great expense of virologic studies at present, considerable effort will be directed toward the development of more rapid, simplified, reliable, and less expensive virus tests. Until such advances are attained, the cost of virologic work will limit these examinations to the more populous States, and to the Federal Government.

FUTURE RESPONSIBILITIES

Discussions of future responsibilities of the public health laboratory would be incomplete without reference to the possibility that the nuclear fission phenomenon may be adapted to diagnostic tests of the future. At the present time the application of radiation in medicine and public health seems more promising in the research field and in control of neoplastic diseases. Yet, one would be foolish indeed to forecast the limitation of nuclear fission to these fields alone. Valuable laboratory tests likely will be evolved from this new and interesting development.

Those of us who have watched the evolution of the public health laboratory remember well the comparatively inactive days of 15 or 20 years ago. Overnight the promotion of the use of serologic tests for syphilis increased many times the total

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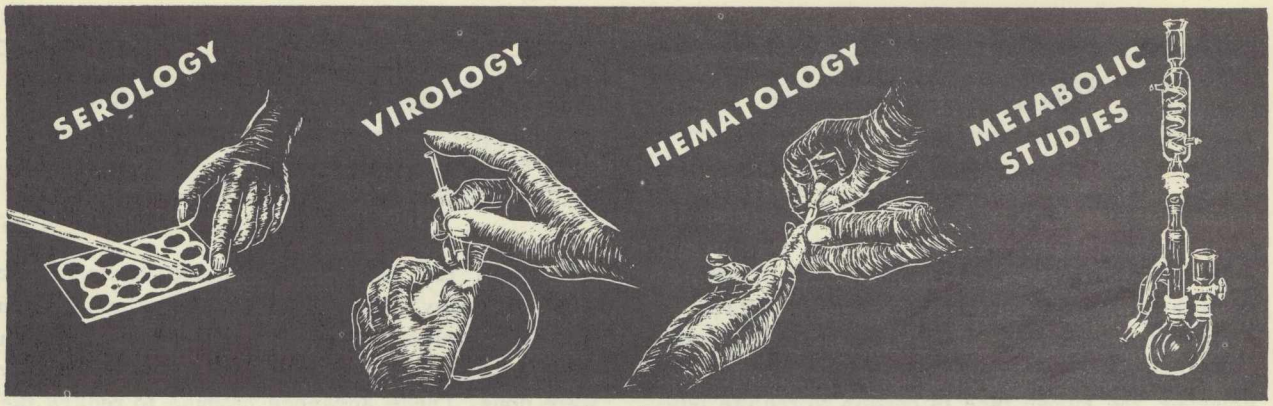

load the public health laboratory was carrying. Indeed, the expansion of the entire health program in the last decade and a half has greatly enhanced the position of the public health laboratory. Today, one specimen is submitted each year to a public health laboratory for each 11 people in the United States, and one laboratory test is performed on these specimens for each 7 people in this country. If medical care programs of one kind and another continue to expand, as seems likely, with the tendency toward utilization of multiphase surveys on an ever-increasing scale, and with the expansion of geriatrics, it is reasonable to expect that the next generation may see performance of at least one laboratory test annually, on an average, for each person in the population.

ESTIMATED GROWTH BASED ON VALUE, ACCURACY OF TESTS

This estimated growth of public health laboratory capacity is based upon the assumption that the value and accuracy of laboratory tests will be maintained or even advanced. There is increasing evidence of gross inaccuracy in the work of some laboratories. The story of the improvement in performance of serologic tests for syphilis in the United States is well known. The same degree of reliability has not been proved in the performance of tests for other diseases. In too many laboratories a feeling exists that a given test is specific, is accurate, and is technically efficient, even though nothing is known of the actual ability of the laboratory and its personnel. Blind belief on the part of some that their laboratory work is infallible indicates great need for such facile humility as was shown by the late Dr. Foster M. Johns of New Orleans, La. In the first evaluation studies of serologic tests for syphilis in the United States, this physician participated with his own modification of the complement fixation test. At the conclusion of the study it was proved that the Johns test was one of two least specific tests evaluated, the other being a presumptive flocculation test. The Johns test also was one of the three lowest tests in sensitivity. Faced with these facts, Dr. Johns publicly admitted the inefficiency of the test and advised all of his colleagues not to use it.

No one can foretell the efficiency of a given test or the performance of a given laboratory unless they are subjected to the most rigid scrutiny. In the Communicable Disease Center during the past year, an evaluation program was set up to determine the relative proficiency of State and Territorial laboratories in the detection of *Endamoeba histolytica* and other intestinal parasites. Forty-two laboratories took part in the evaluation and their performances were controlled by three parasitologists designated by the American Society of Tropical Medicine. When the study began it was hoped that the tests would be performed more accurately than actually has proved to be the case. The reports are now being rechecked before they are published without revealing laboratory identities. Tentative analyses show that there is sufficient variance among the different laboratories to cause doubt as to whether the examination for *E. histolytica* by some laboratories is an aid or a handicap in the detection of the parasite. Indeed, there were 12 specimens of the 110 specimens distributed that were excluded from the evaluation since the referee parasitologists could not agree on the presence or absence of *E. histolytica*. From the foregoing, it would seem that in addition to the question of the ability of the technician to recognize intestinal parasites, there must be fundamental deficiencies in the tests which are used to recover the organisms for identification.

Other evaluation studies of laboratory tests have been conducted but they have been more limited in scope. Dr. E. S. Robinson, a former chairman of the Conference of State and Provincial Public Health Laboratory Directors, made a study on a State-wide basis of the performance of laboratory tests other than syphilis more than a decade ago. Massachusetts has been one of the States that has pioneered in this work. Maryland, Michigan, and New York are others that have made intrastate explorations in this field. The Army of the United States has also conducted evaluation studies, one recently being reported for 14 Army and Air Force laboratories in the Third Army area.* Practically all of these studies show marked discrepancy in test performance by the average laboratory.

NEED FOR IMPROVEMENT IN QUALITY OF TESTS

There is urgent need for sustained, well organized, and intelligent action aimed at improvement in the quality of performance of laboratory tests in the United States. This need has been recognized by the State and Territorial health officers. At the Forty-eighth Annual Conference of State and Territorial Health Officers with the Surgeon General of the Public Health Service, the Communicable Disease Center was requested formally to undertake the evaluation of performance of laboratory procedures other than, and in addition to, the serologic evaluation of tests for syphilis, which that Conference also requested in December 1946. The recent transfer of the Venereal Disease Research Laboratory to the Communicable Disease Center makes available a wealth of experience in laboratory test evaluation, and we are preparing to offer to all State laboratories, on a volunteer basis, the opportunity to study performance efficiency of all laboratory tests for which evaluation methods seem applicable.

CDC IMPROVEMENT PLAN

The Communicable Disease Center plan to improve qualitatively the performance of laboratory tests is substantially the following:

(1) Select and retain only qualified and competent personnel for service in the public health laboratory.

(2) Supplement the experience of capable laboratory personnel by encouraging and organizing:

(a) Formal postgraduate training in appropriate institutions of learning:

(b) Periodic refresher type courses either at headquarters laboratory or in the field;

(c) Laboratory extension and reference service, including detailed consultation on request.

(3) For all State laboratories, establish a periodic evaluation study for each type of laboratory test employed.

(a) In this study, a statistically significant number of specimens will be collected from people known to be free from, and from people known to be suffering with, the specific disease for which the test being investigated is designed.

(b) Some specimens should be taken from persons known to be ill with diseases other than the specific one for which the test under investigation is devised.

(c) Specimens collected and shipped under identical conditions will be in sufficient amount to divide into comparable samples for all participating and control laboratories, but the source of the specimens will not be made known.

(d) If possible, control tests will be performed by the originator of the test under investigation. If the originator is not available, then the control tests will be performed by one or more referees previously agreed upon.

(e) The final evaluation of the test, including the interpretation of statistical data, will be the responsibility of an unbiased and professionally competent group of at least three scientific persons.

(4) A similar intrastate evaluation study should be performed at regular intervals by all local and private laboratories for each specific test performed in such laboratories. The State health department laboratory should direct and be responsible for these intrastate investigations.

FUNCTIONS OF LOCAL, PRIVATE LABORATORIES

In viewing the parts that the Public Health Service and the State laboratories respectively

*Shuey and Cebel: Standards of Performance in Clinical Laboratory Diagnosis, Bulletin of U. S. Army Medical Dept., Washington, D. C., 9:10, 799 (1949).

will play in the provision of public health laboratory services in the future, one should also take into consideration the functions of local public and private laboratories, including State branch laboratories.

Local laboratories constitute the work centers of the national laboratory system. It is in them that all simple, routine, well-established tests should be performed. The State laboratory should be the guardian of this group, should determine the efficiency of their work, and provide consultation for the solution of most common problems. The State not only should encourage these laboratories scientifically, but should provide subsidies in order that laboratory work may be available for persons unable to meet the cost of private laboratory service.

In addition to the above functions, the State laboratory has a responsibility for other aid at the State level that the Communicable Disease Center shares at the interstate or Federal level. It should be responsible in the future for the uniformity and accuracy of laboratory techniques at the local level. It should perform the more difficult, costly, and unusual tests requested at the local level. In addition, the State should provide a reasonably complete intrastate reference service.

The primary function of the Federal Government, acting through the Communicable Disease Center, is that of furnishing consultation to State laboratories and, upon request of the latter, to public and private local laboratories. This broad consultative service should extend to several fields. It should contemplate the development and periodic utilization of methods to insure the quality of laboratory test performance as described above. It should launch a program of methodology research to improve existing techniques and to develop new ones. It should serve as a national reference diagnostic center for the latest information on the examination of difficult and unusual laboratory specimens submitted from State laboratories, and provide also for the performance of more expensive and difficult laboratory tests when requested by State laboratories.

The public health laboratory will continue in the next generation to be one of the most important services offered by the health department. Its individual reports may too frequently be given an inerrant interpretation by the clinician in spite of all reasonable efforts to discourage this practice. The fallibility of laboratory tests must be continually emphasized, yet the State health departments and the U. S. Public Health Service should take every possible step to insure the quality and optimum efficiency of laboratory work.

The provision of competent laboratory service for this Nation in the future is one of the greatest tasks facing organized public health. It will require ample financial support. It will require real team work in a well organized laboratory. And to cover the Nation adequately, it will require a complete and operable liaison of local, State and Federal laboratories.

LEPROSY CONTROL PROGRAM

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HISTORY

Leprosy (Hansen's disease) is one of the oldest diseases known to man. Historians have conceded that the disease was known to the ancient Chinese, Indians, and Egyptians; however, its origin has been lost in antiquity.

Reliable evidence as to when the disease made its first appearance in what is now continental United States is lacking. The earliest available reference to the disease has been found in Romans' *Concise Natural History of East and West Florida* published in 1776, in which reference is made to the occurrence of leprosy in the province as early as 1758. By 1766 the disease had become sufficiently prevalent to cause the Spanish Governor to establish a hospital near the mouth of the Mississippi River for the care of individuals afflicted with the disease..

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