The Developing Role of Laboratories in Chronic Disease Programs

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CHRONIC DISEASE and disability are the major health and medical problems facing our nation today. This is the premise upon which I base this presentation. I do not need to defend the premise with a mountain of statistics. The size of the burden imposed today upon our people by cancer, heart disease, diabetes, arthritis, and a host of neurological and other diseases is well known.

Not only are we faced with new impetus in the attack from chronic disease upon an older, more numerous, and more susceptible population; we are faced as well with the cases of chronic disability which accumulated while we were concerned first with the infectious enemy. In addition, we do not yet know the cause of most of the chronic diseases, much less how to cure or prevent them. Is it any wonder, then, that in dealing with such disease and disability we find ourselves running harder than ever before just to stay where we are?

In examining the role of health department laboratories in this struggle, I am not implying that the traditional services of the laboratory are becoming obsolete. There is the most urgent need to continue and to improve those services with which the laboratory has contributed so much to the control of infectious disease. Each day we gain new evidence that this war goes on, that the organisms we fight are fighting back.

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What I do proclaim, however, is the need in the laboratory and all along the frontier of medical progress to focus more sharply upon the emerging problems of chronic disease. For medicine and science now fight upon two fronts—against infectious diseases on the one front and against chronic disease on the other. It profits us little to debate whether the laboratory should or should not be so committed. The fact is that as a full member of the medical and scientific team the laboratory is committed. The only questions yet unanswered concern how far and how fast laboratories can move toward providing services for chronic disease.

On the basis of past experience I am confident that health department laboratories will take on new responsibilities in chronic disease just as fast as State and national action make this possible. I still recall with amazement, for example, the speed and efficiency with which State laboratories retooled to employ the newly forged weapons of virology.

Unfortunately, retooling and retraining for chronic disease services are far more complicated and far less manageable than previous adjustments, from the administrative as well as the technical points of view.

In the first place the warrant of health department laboratories to deal with chronic diseases is not as well recognized as the traditional mandate to protect against infectious diseases. Nor is the background and training of laboratory personnel well oriented to demands in the chronic disease area. By and large the emphasis in the past has been microbiology rather than biochemistry or pathology.

In addition, the chronic diseases are deceptive and complex. They have symptomless

stages of development and are given to multiplicity. They involve the basic structure and behavior of cells, the chemical composition of the body and the effects of environment upon it. Before we are through we may be dealing with the most basic causes and chemistry of life itself. We indeed lack weapons against such an enemy.

However, we are not powerless. We may not have the best of all possible tests for uterine cancer, but we do have a good test. We may not be able with perfect accuracy to detect in infants the metabolic errors leading to mental retardation, but we are making progress.

As recently as January 1962, Congress authorized an expanded program with additional funds for neurological and sensory disease control. Many of the hopes and plans for this new program in the Division of Chronic Diseases of the Public Health Service are firmly joined to progress in the laboratory. The strong belief exists that in the laboratory will be found, for example, the simplified and improved tests we need to detect phenylketonuria, galactosemia, glycine deficiency, maple syrup disease, histidinuria, Wilson's disease, and other causes of mental retardation.

Diabetes control is another field in which we are particularly encouraged and hopeful. Great strides have been made in developing improved laboratory methods and devices for case-finding. The number of States actively blood testing for diabetes is growing. At present, nearly a quarter million persons per year are screened for diabetes in programs reported to the Public Health Service by half the States.

Advances are being made in laboratory techniques to help the physician predict, diagnose, and treat disorders of the heart and circulatory system. The various laboratory techniques used in conjunction with anticoagulant therapy have been reviewed recently by the Heart Disease Control Laboratory of the Public Health Service, and the results have been published (*1*).

In our efforts against arthritis, we are beginning to move ahead. For example, blood uric acid determination holds the promise of being a practical method of screening for susceptibility to gout, a painful and crippling member of the arthritis family.

Also, we are following closely the development of tests to identify the rheumatoid factor even though we recognize that as yet little can be anticipated in the way of practical preventive measures.

Each day we can do more in the laboratory and in every other phase of medicine and science, if not to prevent the onset, at least to prevent the more serious complications of chronic disease and disability. The key to prevention in this secondary sense is early detection—finding the disease and referring the patient to his physician before overt symptoms can appear—and the key to early detection is the laboratory. More and more the scene is shifting from recognition of disease signs in the examining room to prediction of disease potential in the laboratory. I can think of no more exciting prospect for the skilled and dedicated people in the laboratories of this nation.

Clearly, services for chronic disease are an increasingly vital function of the laboratory, including the State laboratory. How well are laboratories prepared? What are the implications for laboratories in this changing emphasis? To my mind the answers all boil down to standardization and certification.

Standardization

If the physician is to use the results of laboratory work for prediction, diagnosis, or therapy, he must know what the results mean and if they mean the same thing every time. All too often, however, when the physician seeks to interpret the results of laboratory tests he encounters a bewildering variety of techniques, often yielding different values and subject to different interpretations.

For example, numerous techniques are used to measure serum cholesterol levels in the blood. While measuring essentially the same thing, these techniques produce widely different ranges of test values considered normal. Furthermore, the results from a given technique may vary from laboratory to laboratory and even in the same laboratory from day to day. Obviously this is confusing, even to the physician familiar with laboratory procedures.

Quite naturally, physicians tend to mistrust work done in laboratories unfamiliar to them. At best the situation results in loss of time and

energy and duplicate expense when the physician feels he must retest. At worst the physician can misdiagnose or order an unjustified change in therapeutic regimen.

By standardization I do not mean regimentation. The latter is detrimental to the experimentation and initiative so vital to the improvement of methodology. By standardization I simply mean comparability or reproducibility of results. This problem is neither new nor strange to those familiar with the multiplicity of tests which so confused the early syphilis detection programs. In my opinion we are still plagued by such confusion in our testing programs for many of the chronic diseases. If the physician and the laboratory are to work effectively as the first team against chronic disease, this confusion must be overcome.

We are not without leadership dedicated to solving the problems of standardization. Dr. Gerald Cooper and his associates at the Communicable Disease Center in Atlanta offer an excellent example of such leadership. A number of State health department laboratories are actively cooperating in this and other standardization efforts. Much remains to be done, however, and no agency seems better qualified than the State laboratory for the task. Through guidance and direction to private laboratories the State laboratory can help immeasurably the medical profession and the public it serves.

Certification

If proof is required of the need to certify laboratories, we have only to recall the recent accounts of unreliable work and doubtful practices in a few laboratories. In too many States there is neither licensing nor listing of the local private laboratories. In fact, a person totally untrained in laboratory science can often operate a clinical laboratory. Untold numbers of clinical laboratories now operate without adequate supervision or with only token supervision.

The laboratory, of course, has a responsibility to make as certain as possible that all its work is of uniform quality and reliability. But in the final analysis, certification and licensure are State and community responsibilities. Some method of assessing and assuring the quality of laboratory work is essential. In carrying out this responsibility the State or community must police the few. But for the many the need is more often for guidance, consultation, and training. Here again the State laboratory bears a heavy load of responsibility.

Federal Assistance

In 1957, when the American Public Health Association's Committee on Laboratory Services in the Chronic Diseases made a survey, it was found that States most often cited lack of funds as the major reason for not expanding chronic disease laboratory services.

Today, this reason is losing validity. The trend favors financial and other assistance from the Federal Government to States for improving and expanding laboratory services, including services in chronic diseases. The Community Health Services and Facilities Act of 1961 is the latest and most important evidence of such a trend.

Two provisions of this act are of particular interest to laboratories. The first authorizes formula grants to assist States, primarily through public and private nonprofit agencies, in developing community programs aimed at the prevention of disability and the appropriate care of long-term patients. The emphasis is on out-of-hospital programs such as improvement of nursing home care, outpatient clinic services, rehabilitation services, and nursing care of the sick at home. The grants may be used by States to improve and expand activities of the State laboratory. The possibility of using grants to implement and enforce licensure or certification laws is only part of this picture. Through this mechanism we at the Federal level hope to encourage States to provide increased technical assistance and consultation to laboratory directors so that they may improve the scope and quality of their services.

In addition, the States may use grant funds to provide training and education courses to improve the competence of laboratory personnel. I see no reason why States cannot use these funds to contract for services from private laboratories and in this and other ways en-

courage and assist community screening programs.

The second provision of the new law of particular interest to laboratory directors is that authorizing grants for development of improved methods of providing services to the chronically ill. Whereas the formula grants generally seek to assist in initiating and expanding community services of established types, the project grants stress experimentation and demonstration to develop new and better methods of providing services. More than 160 applications for these project grants have been submitted, representing nearly every State. More than 70 applications have been approved and funded. Hopefully, the State laboratory will be able to share in this opportunity to investigate and experiment to benefit increasing millions of chronically ill and impaired persons.

Still another program with strong implications for the State laboratory is the new research grants program being developed in the Division of Chronic Diseases of the Public Health Service. The program is patterned largely after the research grants program at the National Institutes of Health. The difference is that we seek to encourage applied rather than basic research. We are particularly interested in:

1. Development, refinement, adaptation, and evaluation of screening and diagnostic tests which can be applied to large groups in order to simplify, accelerate, reduce the cost, or improve the reliability of early detection of chronic diseases.

2. Coordinating, organizing, recording, and providing care and related services, including laboratory services, to the disabled, aged, and chronically ill in a variety of settings.

3. Development and use of instruments such as electromechanical testing devices.

4. Development and use of new procedures and techniques in the detection as well as the management of chronic diseases.

Summary

In public health, emphasis is shifting from the infectious to the chronic disorders. The laboratory has the responsibility to help physicians predict the implications of cellular and chemical change before symptoms appear and thus expose chronic disease before it causes serious damage. Present trends in legislation and programing indicate increasing support of laboratories from Federal-State activities.

REFERENCE

(*1*) U.S. Public Health Service, Heart Disease Control Laboratory: Laboratory techniques in the control of anticoagulant therapy. Prepared by Marguerite L. Chandler. Preliminary edition. U.S. Communicable Disease Center, Atlanta, Ga., revised May 1962.