Quality Clinical Laboratory Services for the American People

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ALTHOUGH those close to the clinical laboratory have long recognized that laboratory errors can occur, the problem has not been openly discussed until recently. Walter Cronkite in a Columbia Broadcasting System program in 1965 focused attention on the poor performance of certain mail-order laboratories and stimulated, in part, the introduction of bills in Congress to establish performance standards for clinical laboratories engaged in interstate commerce.

In testifying before a Senate subcommittee, Dr. David J. Sencer, director, National Communicable Disease Center (NCDC), cited proficiency testing studies that demonstrated significant degrees of unsatisfactory performance in various fields of clinical laboratory work (*1*). Although the results varied from laboratory to laboratory, he concluded that "this information indicates that erroneous results are obtained in more than 25 percent of all tests analyzed by these studies." As might be expected, this statement caused great concern and, at first, certain groups challenged 25 percent as being too high a percentage or maintained that it applied to laboratories other than their own. Others have maintained that this percentage is too conservative.

Although scientists in clinical laboratories would like to be immune to error, there is no reason to expect human beings and machines to obtain perfect results in a clinical laboratory when they do not elsewhere. Additional objective evidence obtained since 1965 makes it unnecessary to belabor the point that medical laboratories can make errors or to debate the extent of the errors. All types of medical laboratories—independent, hospital, and public health—are now generally recognized to be subject to error, and we can therefore proceed with the task of improving laboratory services.

A number of significant programs and cooperative efforts have been started which should result in major improvements. Only a few can be considered in this discussion, but they illustrate what must be done to provide quality laboratory services for the American people.

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Legal and Regulatory Efforts

Until recently, there has been little or no governmental control of clinical laboratories. Beauty parlors, barber shops, and their operators are licensed in most States and cities, but the clinical laboratory and the personnel who examine blood specimens and throat swabs

from patients, have been allowed to operate without control.

The first nationwide effort to establish controls for clinical laboratories came through the program of Health Insurance for the Aged (Medicare). The Medicare regulations (*2*) developed by the Public Health Services' Division of Health Standards established specific standards that State agencies follow in certifying laboratories as qualified to receive payment for tests under Medicare. Significantly, however, the law prohibits the application of these standards to laboratories in hospitals—although probably more than half of the laboratory tests (approximately 700 million) are performed in hospitals.

State control has evolved slowly, but it is now gathering momentum. When the Medicare program began in 1966, only six States required some form of laboratory licensure. Currently, 19 States, New York City, and Puerto Rico have laws or policies requiring the licensure of clinical laboratories and laboratory personnel, or both. Many other States have licensure legislation in various stages of consideration. Some present laws, for example, those of New York State, New York City, Kentucky, Tennessee, and Puerto Rico, provide for progressive regulations which will lead to laboratory improvement; others do little more than maintain the status quo in accordance with the vested interests of the existing laboratories.

Guidance is available to those interested in the enactment of good local laws to improve the performance of laboratories. In 1966, NCDC prepared a comprehensive guide (*3*) for such suggested legislation, and in 1969 the Council of State Governments published a model bill (*4*) to assist State legislatures in drafting licensing laws for regulating the clinical laboratory.

The Clinical Laboratory Improvement Act of 1967 (CLIA), P.L. 90–174, provided for Federal licensure of clinical laboratories (independently and by hospitals) that are engaged in interstate commerce. This law is serving, even more than Medicare, as an impetus to the development of local regulations. The act exempts clinical laboratories in States that enact laws establishing standards equal to, or more stringent than, those of the interstate regulations.

In addition, CLIA of 1967 is refining still further the Federal standards for licensure of clinical laboratories. Working with several ad hoc committees whose members are clinical chemists, microbiologists, pathologists, bioanalysts, and technologists, NCDC has developed regulations (*5*) which are being used in the interstate licensure program.

Although until now Medicare regulations have emphasized qualifications of personnel, the CLIA regulations have emphasized the accurate performance of the tests through proficiency testing programs and internal quality control. The Division of Health Standards of the Service and NCDC are working together to make Medicare and interstate regulations as uniform as possible.

Hopefully as new State laws are enacted, they will provide for laboratory improvement programs which will meet the CLIA requirements and the existing deficient laws will be revised to conform with Federal standards. In this way, most clinical laboratories in this country eventually would operate under comparably high standards of performance.

Private Improvement Efforts

Several private professional organizations have constructive programs for regulating and improving clinical laboratories.

As stated earlier, Medicare standards for independent laboratories cannot be applied to hospital laboratories. This exemption occurred because Medicare provided that laboratories in hospitals accredited by the Joint Commission on Accreditation of Hospitals were automatically eligible to participate in Medicare and, in addition, that the laboratories in other hospitals cannot be subject to Medicare regulations that exceed the Joint Commission's standards. The laboratory requirements for the Commission's approval have been far below those of Medicare and, as a consequence, a double standard has resulted which has seemed unfair to the independent laboratories. The Commission is revising its standards, and this revision is expected to bring the standards more in line with those of Medicare. Hopefully, these improved standards will be implemented in the near future.

The College of American Pathologists

(CAP) has expanded its laboratory improvement activities by initiating its "programs of excellence." These include laboratory surveys (proficiency testing programs) that cover all areas of laboratory work, laboratory inspection, and accreditation. Commendably, its proficiency testing programs are no longer limited to members of the college but are available to any laboratory which wishes to subscribe.

The laboratory accreditation program of the College has been accepted as a substitute for Federal evaluation for interstate licensure under CLIA. To date, it is the only private program to adjust its standards to comply with those established for interstate licensure.

Although exact numbers are unavailable, it is estimated that more than 300 million tests are performed in the offices of physicians in private practice. Practically all existing laws, both Federal and local, exclude from regulation those laboratories in the offices of one or two physicians who perform tests primarily for their own patients. Laboratory services performed under these circumstances are considered to be the practice of medicine.

Some of the laboratories that are presently subject to regulation are concerned over this exclusion, particularly since they reason that a comparable percentage of error may occur in these private office laboratories. Although this situation constitutes a deficiency, at this time efforts should be concentrated on making it possible for all organized laboratories—independent, hospital, and public health—to operate under comparable standards of quality.

The American Society of Internal Medicine is interested in seeing that quality laboratory service is performed in the offices of physicians in private practice. In cooperation with the Division of Health Standards of the Service, the Society has canvassed its members about participation in a 1-year proficiency testing program to determine the level of competency with tests for urea nitrogen, hemoglobin, and glucose. Recently, the American Society of Internal Medicine gave the Service a list of 500 internists who are interested in participating.

The CAP has developed a special office laboratory survey (proficiency testing) so that physicians can monitor regularly the performance of their laboratories. Because of the increased complexity of laboratory work, the increased automation, and the need for specialized laboratory competencies, the amount of laboratory work performed in office laboratories will probably decrease. Nevertheless, these constructive efforts of the internists and pathologists are commendable and important because laboratory work in physicians' offices will probably continue to be excluded from regulatory legislation in the foreseeable future.

Standardizing Reagents and Materials

One cause for variations in laboratory results is the variability of reagents used in diagnostic tests. Considering the variety of antigens, control serums, chemicals, stains, and mediums needed by the clinical laboratory and the number of companies that manufacture them, setting standards constitutes a major difficulty in laboratory improvement.

The National Bureau of Standards shortly will have available 10 standard reagent materials for clinical chemistry determinations. The Laboratory Division of the National Communicable Disease Center has described specifications for approximately 900 microbiological reagents. Reference reagents meeting these specifications have been prepared and are available to reagent manufacturers and to national and international public health agencies. Although the Federal standardization efforts of the National Bureau of Standards and the National Communicable Disease Center have been undertaken with the cooperation of manufacturers and in consultation with outside specialists, there has been a need for even greater cooperative efforts.

Recently, a significant step was made in the direction of standardization. Through the initiative of the standards committee of the College of American Pathologists, an independent National Committee on Clinical Laboratory Standards was organized in April 1968. Membership is open to all industries, professional organizations, and government agencies that have an interest in the clinical laboratory field. Currently the membership is 50—31 industrial representatives, 16 professional representatives, and representatives from three Government organizations. Each member appoints a represen-

tative and an alternate and submits names of persons available for assignment to area committees or working groups as experts in their areas of interest.

The objectives of this committee are to promote the development of national and international standards, such as written specifications for reagents and equipment, through a mechanism which insures that consensus has been obtained by all interested groups. Task forces and working committees have been organized to develop and propose standards for the fields of clinical chemistry, blood banking and immunohematology, microbiology, hematology, and instrumentation.

Laboratory Manpower

We do not know exactly how many people are engaged in clinical laboratory work in this country, but some have estimated as many as 100,000 (*6*). In any event, acute shortages of well-qualified persons exist, and we anticipate greatly increased demands for trained personnel to meet expanding health needs, such as Medicare, Medicaid, mass screening programs, and the new technology. In the past there has been considerable support for research training but little for the training of persons seeking careers in the diagnostic laboratory. Fortunately, emphasis is beginning to be placed on training for services.

Through the Division of Allied Health Manpower and Regional Medical Programs, educational facilities are being established or expanded for training clinical laboratory assistants and medical technologists and for specialization to the master's degree level of medical technologists.

Training of other specialists, such as clinical chemists and microbiologists, has been neglected; however, four national conferences on training held in 1967 (*6–9*) recognized that the present and future clinical laboratories must be staffed by specialists. For instance, the report (*10*) of the conference convened by the National Institute of General Medical Sciences recommended financial support of postdoctoral residency programs to prepare the required specialists for the diagnostic laboratories.

The most encouraging feature of these current trends and programs that may bring about significant improvement in clinical laboratory performance is the extent to which the various interested groups are working cooperatively toward a common goal.

Public Health Service Responsibilities

We in the Public Health Service are participating both directly and indirectly in this national effort to improve clinical laboratories. In the Public Health Service Hospitals, Indian Health Service Hospitals, outpatient clinics, and Federal prisons, we have a direct responsibility to assure that competent laboratory service is provided for the patients under our care. In 1964 the chief, Division of Hospitals, invited laboratories in Public Health Service installations to participate in the Center's proficiency testing programs. By 1967, 75 of these laboratories were participating in some phase of the program and as of now, 118 are receiving regular shipments of test specimens in one or more fields.

A number of the pathologists and technologists in the large Service installations have taken NCDC laboratory courses, but there is a definite need for greater consultation and training, particularly for technicians working in the smaller hospitals and clinics. Since Federal laboratories are exempt from legal regulation, we must make certain that Public Health Service laboratories meet the standards required of others.

Indirectly, through programs associated with Medicare, Medicaid, interstate laboratory licensure, and services to States and municipalities, the Public Health Service has the responsibility to assist in improving the performance of laboratories at all levels throughout the country. The consultation and training program of the laboratory division at NCDC is dedicated to assisting the State public health laboratories to improve their diagnostic competencies and to provide the States and others with guidance and help in the training of personnel in laboratories at local levels.

Laboratory improvement, however, constitutes a tremendous undertaking requiring the cooperative efforts of Federal, State, and municipal health departments, academic institutions, professional organizations, and industry.

Concerted, continuous programs are required to provide consultation, training, and other assistance needed by the 12,000 to 14,000 clinical laboratories in this country.

With assurance of payment of laboratory bills through health programs, the development of automated laboratory procedures, the establishment of mass screening programs, and the growth of comprehensive health insurance plans, the number of laboratory tests in this country may increase from an estimated 1,300 million now to more than 3 billion by 1975. Although our ultimate objective in laboratory improvement is to upgrade patient care and prevent needless human suffering, a tremendous economic savings will result as laboratory analyses become more and more accurate.

In summary, the clinical laboratories of this country have significant difficulties. Fortunately, Federal and State agencies, professional associations, and academic institutions are accepting the challenge of laboratory improvement and have made commendable strides toward desirable goals.

We in the Public Health Service must be deeply involved in this challenge. First, we need to make certain that our patients receive the highest quality of laboratory service. Second, we need to assist and support constructive programs of others that are directed toward bringing quality laboratory service to all segments of the population.

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Tearsheet Requests

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