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THE ROLE OF THE STATE LABORATORY IN EVALUATION  
OF PERFORMANCE

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## THE ROLE OF THE STATE LABORATORY IN EVALUATION OF PERFORMANCE

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Prologue: Since my presentation at the Conference in Detroit, November 12, 1961, was largely *ex tempore*, I have taken the privilege of writing words here that I may not have uttered. I have also taken the liberty of adding a few quotations from material not available to me at the time of the Conference. However, I have preserved the ideas as originally expressed and the conclusions to which I have been led. On re-writing, I find no reasons to change these views. However, I have been led to a new sense of urgency for us all to initiate realistic evaluation programs by collaborative effort of all concerned. If the present writing seems to sermonize on the subject of evaluation, it is so intended!

Much of the thinking regarding evaluation of performance in medical and health laboratories is related to quality control, both intra- and inter-laboratory. While this is an important aspect of evaluation of performance, a total program encompasses other activities necessary to attain a proper appraisal. Most of the papers read at this morning's session of the Conference have dealt with separate aspects of the total problem of laboratory evaluation.

There is nothing new in the presentation to be given today — nothing that has not been said by others many times before and perhaps better. However, there is a new sense of urgency in meeting our responsibilities, highlighted by the reports from New York City and elsewhere. Please do not make New York City the scapegoat. We are all aware that, to a greater or lesser degree, the same sort of thing is going on in our own areas.

The time has arrived, if it has not already passed, when those who have responsibilities for developing comprehensive systems of evaluation must do something about organization to meet the problems. The latter have been repeatedly identified in the last dozen years or more. Echoes of the past keep coming up and there is needless activity related to identifying the already apparent problems and the needs for evaluation.

Commendable beginnings have been made to meet these needs by national scientific and professional groups. The College of American Pathologists, the American Society of Clinical Pathologists, the American Association of Bioanalysts, the American Association of Clinical Chemists and others have, for some years, developed and expanded programs of voluntary inter-laboratory quality control for members who have subscribed. Some have gone beyond this activity and instituted scientific and professional educational programs.

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A recent statement in the Bulletin of the College of American Pathologists, Vol. XV, No. 11, November 1961, announces their accreditation program as follows:

"The College is instituting an accreditation program for clinical laboratories. This program will be voluntary in that each laboratory desiring accreditation must ask for it. A survey of the facilities, equipment, personnel and performance of the laboratory will be made following a request for accreditation to determine whether the laboratory meets the standards which must be met for accreditation. Laboratories in hospitals and pathologists' private laboratories will be eligible to participate in the program."

There is a growing recognition of the need beyond inter- and intra-laboratory quality control for full evaluation and accreditation of laboratories. While quality control is a commendable objective, it is nevertheless a most formidable undertaking when viewed from the national level. It presents major logistic problems to cover the needs on a national level of all the laboratories engaged in diagnostic services in medicine and public health. It is difficult to see how a 100% coverage is attainable. Even on a State level, such a program to be effective, presents great problems that need resolution. The matter of sending out all sorts of "unknown" evaluation specimens at regular intervals is one fraught with logistic difficulties that will require the full time services of a specially designated staff. The statistical analysis of the results of reporting laboratories further requires expert treatment of data to yield usable results.

Research must be developed to determine the character and validity of such unknown specimens. Inspection of facilities, refresher education of personnel must be a regular continuing activity.

Thus far, I have attempted to indicate the enormity of the problem of inter- and intra-laboratory quality control on a national level and some indication of its magnitude on a reduced State level. Regardless of the divisiveness of opinions on who should, or who should not, be conducting the kinds of laboratories we are discussing, we must be realistic in our approach and consider the fact that all kinds of laboratories *do exist*, that their directorships cover all shades of training, experience and professional qualifications. Since all serve the public, there is equal need that they serve in an acceptable manner and maintain high standards of performance.

Up to this time, as commendable as the efforts of private and public groups have been to meet the needs of evaluation, we must admit that we have been pecking away at a major problem of huge proportions. If quality control, covering all laboratories on a national level, appears to lack feasibility, certainly a complete evaluation program covering all the facets enumerated, will be equally unattainable. So long as we spend our energies in repeatedly identifying the problem, so long as we emphasize the quality control features of evaluation as an end, so long as we attempt to meet the needs on a national basis divided by the varying interests of national professional, scientific and technological groups —

so long will the solution of the major pressing problem suffer continual and dangerous delay.

If we can reduce the area of responsibility from the national level to the state level, there is a good chance that our objectives can be accomplished, provided there exists a will to do it, provided that all concerned will cooperate in the development of an effective and acceptable program.

In most States, there is already a body of experience in conducting performance evaluation programs under the aegis of the State Health Department Laboratories. True, this experience has been confined, for the most part, to approval systems for syphilis serology and bacteriology of communicable diseases. There has been a ready acceptance of the State Laboratory in these fields. They have, for years, demonstrated that their evaluation programs have yielded improved standards of performance. Thus, there is already present in each State, a framework upon which to build an attainable program of laboratory evaluation, in the full meaning of the term. Such a state program is feasible if all professional, scientific and technological groups cooperate with the State Laboratories in setting up a modus operandi. The State Laboratory cannot, and should not "go it alone"; they will need all the advice and consultation with the representative groups of laboratory scientists.

In short, a full evaluation program as we have envisioned, suffers defeat at the outset by its magnitude on a national level, but becomes realistic and attainable on a state level. That the State Health Department Laboratory should be assigned the role of leadership is a fortunate happenstance. Even at this level, it can be an enormous undertaking requiring man-power, know-how and budget support. There is generally a reluctance to have a governmental agency undertake such an activity. Some may view this as a "policing" affair not in the province of a health department without statutory responsibility. It is not to be expected that there would be a unanimous acceptance of any state plan. But, realistically, we must admit that it is the only plan brought forward that has a chance of success.

I am sure that I shall not find unanimity even among the State Laboratory Directors. As Dickman pointed out in his Conference presentation of 1957, State Health Departments have generally assumed the responsibilities for evaluating laboratories in venereal and communicable diseases. Why should we limit these Health Department responsibilities to these two categories in the public interest? The growing interest of public health in chronic illness, mental health, effects of radiation, air and stream pollution, food and drug surveillance, etc. — all require laboratory support. If these programs are to be effective, the laboratory participation must yield reliable data. The privately practicing physician is entitled to know that the laboratory he is using for study of his patients is performing in an acceptable and ethical manner.

The American Public Health Association, Laboratory Section, has made some progress in studying the problems of laboratory evaluation. Contact with national scientific and professional groups has been estab-

lished. There is a growing tendency for all concerned to work together and develop a modus vivendi. Dr. F. C. Coleman, in his Presidential address at the annual meeting of the College of American Pathologists (October 3, 1961), discussed the Standards Program of the College and made the following important statement:

"Recently the Standards Committee was authorized to make the college evaluation surveys such as those in clinical chemistry and microbiology, available to Laboratories *other than those directed by pathologists*. Such requests must come, however, from individual applicants who have reasonable scientific interest in the medical field."

This is a noteworthy change in policy and the College of Pathologists is to be highly commended for this forward step in making its contribution available to selected applicants.

I take personal pride in the fact that in New Jersey, good will and close liaison has been established between the Health Department Laboratories and private groups. One such group is now working for the establishment of a voluntary evaluation system of its members to be carried out by the State Department of Health. Serious consideration of the same sort is to be given by another important group of professionals. We are drawing closer together to meet a common need and purpose. Such relationships in this changing world can be attained in every state if proper liaison is established; if we rid ourselves of reactionary thinking and become realistic, without sacrifice of basic principles.

Thus far, the points I have made are:

- 1) The need for evaluation of performance of all laboratories in the medical and public health field has been adequately established.
- 2) A fully adequate evaluation program encompasses a number of important facets.
- 3) The magnitude of carrying out an effective program from a national level makes it unfeasible, but attainable on a state level.
- 4) The agencies best suited to institute such a program by reason of experience and status, are the State Public Health Laboratories.
- 5) Working and consulting with private professional and scientific groups, a realistic and effective program can be established.
- 6) The State Laboratories are in a position to implement all the facets of a full evaluation program and to utilize resources not readily available to private groups.

And now, I arrive at a place in my contemplation of the evaluation scene, that gives me mental and spiritual pain! In more recent days, especially, I have been "wrestling with the Spirit," as the Quakers might

say. The pain I refer to is that which comes to us when, after due reflection, we must change a deep-seated opinion. The cerebral substance, when grooved by a long-time period of thinking in a certain way and having to undergo a re-arrangement of its cells to be regrooved in a new line of thought, must occasion pain! For many years, I carried the conviction that evaluation programs could be established and could succeed on a voluntary participation basis. During these years, I have preached this doctrine for the reasons that 1) most of us want to do a good job, 2) most of us want to know whether we are doing a good job and 3) the fractional percentage of those who are not so-willed will "see the light" and eventually reform and join.

After deliberative thinking, I have now changed my view; time is of the essence; we cannot await an "evolutionary process" to attain our objectives. If our laboratories are to receive the benefits of a full evaluation program, if the public interests are to be protected, no laboratory can elect to remain outside the pale of evaluation! I yield from a cherished hope of a voluntary system of evaluation to one of a compulsory nature. Perhaps, eyebrows will be raised at this statement and I am sure I shall hear about it from many sources, including my best friends. There is bound to be a difference of opinion and I would welcome discussion based on facts and principles without unwarranted dogmas.

At first blush, compulsory evaluation smacks of a "policing" job, especially if enforcement is in the hands of a governmental agency. Some may argue that this is another example of the inroad of government into private affairs. This need not be so, if such a compulsory evaluation program is properly developed as a joint effort of private groups with a governmental agency.

I cannot cover here all the details of the deliberations that have led to my conclusions. There are no evils or devils in what has been suggested. "The greatest good for the greatest number" is still a guiding democratic principle upon which our nation was founded and upon which our laws are based.