Health Department's Role in Improving Operations of Clinical Laboratories

MORRIS SCHAEFFER, M.D., Ph.D.

WITHIN the past three decades, a curious and contradictory phenomenon has evolved in laboratory medicine. During an era of advancement in the biological and chemical sciences, research laboratories have flourished beyond expectation, but the service laboratories have not kept pace. This has occurred though physicians and health officers require more and greater varieties of services from clinical and public health laboratories.

What is the reason for this paradox? The factors are manifold and complex. Several are strikingly important common causes. These include the profound economic changes since World War II, increasing attractiveness of industrial and Federal research positions, vast growth of funds available for research, and lack of trained and motivated personnel.

In the management of infectious diseases, for example, the advent of one antibiotic after another, providing a false sense of therapeutic security, has all but eliminated the diagnostic microbiology laboratory. As if to compensate fundamental developments from the antibiotics, include tissue culture techniques and modern virus vaccines. Yet, applied medical microbiology is almost a lost art and few medical bacteriologists are being trained to replace the rapidly dwindling handful of old ones. The situation may not be quite as sad in other areas of clinical laboratory practice, but it is troublesome in many of them.

Dr. Schaeffer is director of the bureau of laboratories, New York City Department of Health.

Adequate medical care is impossible today without the prompt service of a reliable diagnostic laboratory. The proper choice and utilization of antibiotics in infections, control of electrolyte levels in the treatment of heart and kidney disease, restoration of normal function in metabolic and endocrine disorders, and the treatment of cancer in its earliest detectable stages, all depend upon the laboratory for diagnosis. Many other conditions are accompanied by increasing demands on the laboratory, including the extensive use of blood and blood products to permit the application of newer surgical techniques to the treatment of chronic heart and lung disease and the regulation of nutritional defects in aged patients and those with chronic gastrointestinal and liver disease.

The mounting complexity of these tests and growth in demands for direct patient service makes the good hospital laboratory of a decade ago obsolete today. Many administrators fail to recognize this situation and, indeed, many neither encourage nor permit their laboratories to improve physical facilities or obtain the adequately trained personnel needed to meet the challenges of advancing medical science.

The state of affairs is not limited to one city or State. Unfortunately it is a universal ill, which has been generally ignored by the individuals who should be most concerned, physicians, public health officials and educators.

New York City's pioneer efforts in the supervision of clinical laboratories took root nearly 50 years ago. Shortly after World War I the Sanitary Code of the City of New York was

amended to make the health department responsible for the supervision of clinical laboratories. The sanitary code was again amended in 1925 to establish requirements for laboratory directors and provide for physical examination of laboratory premises as well as practical examination of technical personnel. Responsibility for enforcement of code regulations was placed within the bureau of laboratories.

Cognizant of the steady decline in clinical laboratory performance, the bureau began conducting more frequent laboratory inspections and performance tests in 1960. The office of supervision of clinical laboratories and blood banks was reorganized and restaffed to coordinate these programs. The object was to determine particular areas of weakness and to devise methods for improvement. The results of such laboratory surveys are shown in tables 1 and 2.

Frequent laboratory visits also pointed out the weaknesses of the provisions of the health code (formerly the sanitary code). After 2 years of study, department personnel, with an advisory committee of experts in laboratory medicine rewrote Article 13 of the health code, and the new regulations for laboratories were adopted by the board of health in February 1963.

The new provisions clearly delineate standards for laboratory practice and set forth the requirements for personnel at all technical levels. Only those persons who meet these criteria are issued the certificates of qualification, required for employment in a clinical laboratory. All laboratories submit applications for operating permits and demonstrate competence in performance as well as satisfactory compliance with other code regulations.

There existed in New York City in 1965 about 20 municipal hospital laboratories, 45 proprietary hospital laboratories, 90 voluntary hospital laboratories, and about 200 commercial clinical laboratories. In addition, there are about 45 blood banks, making a total of about 400 laboratory establishments. These laboratories and the health department's public health laboratories serve about 20,000 physicians practicing within the city.

More than 500 people are employed by the public health laboratories of the city health department. The annual budget is well over $3 million. In addition, the Public Health Research Institute, with a separate budget and under separate administrative aegis, carries out basic research. The institute shares the physical facilities occupied by the bureau and assists the health department in certain areas.

The unit responsible for the supervision of clinical laboratories and blood banks was recently renamed the division of laboratory field services. It spends about 10 percent of the bureau of laboratories' budget at its present level of operation. There are capable and dedicated personnel in this unit but a core of highly skilled and professionally recognized experts in the various branches of laboratory medicine is still needed. Such individuals are essential to the success of the mission. They must have the respect of the community of laboratories and be capable of rendering assistance and training at the high levels required by many laboratories for raising standards of performance.

Even within the limited scope of our present operation, we have been able to assess the weaknesses inherent in many of the clinical laboratories visited and we have been influential, to some extent, in their improvement. Tables 1 and 2 show how generally poor the performances have been with some improvement since 1960. It is evident from these data that the majority of laboratories still cannot be considered satisfactory.

The crux of the matter rests, in my opinion, in the initiation and maintenance of an effective surveillance and improvement program. This requires highly trained personnel who are leaders in their field and who would gain ready acceptance by the laboratories which perform poorly. Consultation and training, rather than police techniques, would provide a greater incentive for improvement. Additional funds have recently become available through a Federal grant and some of the required personnel are now being recruited.

The lasting success of this project will depend greatly on the methods employed in attempts to improve laboratory performance. For this reason it is proposed that we identify this activity by the more appropriate name of laboratory

improvement program. Our objectives have the full support of the medical community, and the fact that we are approaching the problem as a physician would an illness is particularly appreciated. First the illness is diagnosed, then it is treated. Finally preventive measures are instituted to maintain the "patient" in a healthy state.

A tentative diagnosis has been made. With more careful observation and study, the existing ills will be more accurately assessed. The specific remedy and most effective methods of prevention remain to be determined. However, it is generally agreed that a training program, designed to correct the weaknesses uncovered by an intensive program of performance testing, would yield the maximum results.

A properly developing and well-supported program would include the following activities.

- Development of an efficient system for as-

Table 1. Performance tests in bacteriology, serology, and clinical chemistry of clinical laboratories, New York City, 1960–64

Type of laboratory and date	Bacteriology			Serology			Clinical chemistry		
	Number tested	Unsatisfactory		Number tested	Unsatisfactory		Number tested	Unsatisfactory	
		Number	Percent		Number	Percent		Number	Percent
Proprietary hospital:									
1960–62	31	23	84	22	3	14.0	35	19	54
1963	31	14	45	46	14	21.7	69	17	25
1964	49	19	39	39	4	10.0	68	17	25
Voluntary hospital:									
1960–62	60	39	65	55	5	9.0	68	22	32
1963	25	7	28	95	9	9.5	120	16	13
1964	54	26	48	44	8	18.0	66	10	15
Commercial:									
1960–62	87	69	80	120	21	18.0	149	57	38
1963	30	22	73	144	20	14.0	195	32	16
1964	50	26	52	69	13	19.0	1000	18	18

Table 2. Performance tests in blood grouping and typing and cross matching for transfusions, clinical laboratories and blood banks, New York City, 1960–64

Type of facility and date	Grouping and typing			Cross matching		
	Number tested	Unsatisfactory		Number tested	Unsatisfactory	
		Number	Percent		Number	Percent
Proprietary hospital:						
1960–62	37	2	5	33	15	45
1963	69	4	6	69	14	21
1964	68	11	16	66	13	20
Voluntary hospital:						
1960–62	67	7	10	64	12	10
1963	107	8	7	101	26	26
1964	69	8	12	67	17	25
Commercial laboratories:						
1960–62	104	16	15	----------	----------	----------
1963	133	10	8	----------	----------	----------
1964	60	11	18	----------	----------	----------
Commercial blood banks, 1964	9	0	0	----------	----------	----------

sessing the competence and performance capability of clinical laboratories and blood banks.

- Supplying reference specimens for self-examination by laboratories on a routine basis.
- Increasing the rapport between clinical laboratories and the health department by offering a consultation and training program.
- Serving as a reference laboratory for the clinical laboratories in the community.
- Demonstrating that the improvement of clinical laboratories can improve the medical care of ambulatory patients and reduce the bed days required for hospital patients.

INTERNATIONAL MAIL POUCH

Communicable Diseases in Ethiopia

The Government of Ethiopia published the first official report on communicable diseases in that country in March 1965. The Anti-Epidemic Service of the Ministry of Public Health compiled the statistics for the decade 1954–63 from monthly reports submitted by each provincial health department to the medical statistical officer.

The monthly reports record the outpatients and inpatients seen in the hospitals and clinics, including health centers. The statistics are affected by the fact that the first group is diagnosed by dressers, health officers, and physicians; the second group by health officers and physicians only. The case fatality rates are small compared to the morbidity rates because a death registration system has not yet been established.

The 10-year report is introduced by a discussion of several factors affecting the reporting and occurrence of communicable diseases. This section includes background information about the geography, climate, and population of Ethiopia and the progress which has been made in the public health field.

Historical descriptions of selected communicable diseases—malaria, smallpox, the typhoid paratyphoid group, typhus, and rabies—are given along with data from the monthly reports on outpatients seen in the hospitals and clinics in Ethiopia during 1959–63. This provides an approximate picture of morbidity, mean of monthly incidence, percentage, and seasonal index by month.

The mean of monthly morbidity given for malaria varies from 76.6 in March to 148.5 in November. The trend is for an increase in morbidity from September through November and a decrease from December to March.

Another section of the report shows the monthly and yearly morbidity and case fatality of 23 selected notifiable diseases seen in outpatients and inpatients in each province during 1954–63. The morbidity of selected communicable diseases seen in hospitals, by province and by month, 1959–63 and by age and sex for 1959–63 are given in the final sections.

This first official report presents data collected over a 10-year period to give the general picture, show trends of common communicable diseases, and provide a record for future comparisons. The Ministry of Public Health hopes to follow the 10-year report with regular publication of annual reports.

Nutrition Survey in Guatemala

Under a contract with the National Institute of Child Health and Human Development, Public Health Service, the Pan American Health Organization is performing a nutrition survey among isolated Indian and Ladino villages in the Guatemalan highlands. Among the villagers with similar genetic, socioeconomic, geographic, and cultural makeup, malnutrition is common and fairly evenly distributed.

The study will explore the effect of nutritional status on physical growth and mental development of children from the newborn period to school age, determine at what age nutritional supplements promote changes in growth and development, and study the cultural and socioeconomic factors that influence growth and development at various ages.

Approximately 200 children born annually in each village will be studied to age 6 by personnel of the Institute of Nutrition in Central America and Panama. Project personnel will be stationed permanently in each village to provide daily food supplements to the children on a voluntary basis.