Progress in Clinical Pathology

The University of Minnesota Issue

Editors
Mario Stefanini
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VOLUME VIII

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Preface

Nineteen-eighty finds laboratory medicine facing new challenge and new opportunity. The challenge is that of ensuring proper utilization of laboratory data; the opportunity is that of improving patient care. A quarter of a century ago, the clinical laboratory was a small manual operation. Today it is a sophisticated system of immense analytical capacity. Over the past 25 years, laboratory medicine has been remarkably successful in bringing scientific and technological innovation within reach of the practice of medicine. It is now apparent, however, that the clinical laboratory generates more information than the clinician can reasonably assimilate, and herein lies the source of new challenge and new opportunity. The onus is now on laboratory physicians—mostly clinical pathologists—to ensure that laboratory tests are put to proper use. Laboratory medicine's predicament is summarized nicely by Carter and his associates:*

> To regard an increasing . . . work-load solely as a challenge to be met by ever-increasing automation and centralization may cause more problems than it solves. Rising demand must be recognized as, in part at least, a symptom of poor communication between wards and laboratories. Long-term solutions should involve the . . . pathologist at the requesting end of the chain. It seems important to keep laboratories to a size within the pathologist's span of responsibility, and for . . . pathologists to take every opportunity to communicate with their clinical colleagues. The alternative to supplying both results and an opinion on them is to continue introducing systems in which unexpectedly necessary or urgent results may be lost among the fast-rising numbers of clinically unnecessary tests. These large general laboratories, showing low unit costs, may not be more economical than more local laboratories with smaller outputs where pathologists have a sufficiently detailed knowledge of their staff and department's work to give an opinion for which they are fully answerable. In so doing they will influence clinical practices.

The year 1980 finds most community hospital laboratories in the United States staffed by pathologists certified in both anatomic and clinical pathology. Most are generalists in the sense that they direct and provide consultative support for all areas of the laboratory. In the words of Carter et al., these pathologists "have a sufficiently detailed knowledge of their staff and department's work to give an opinion for which they are fully answerable."

The year 1980 also finds most larger hospital laboratories—in particular, medical school departments and their major affiliates—organized into departments of pathology and laboratory medicine. Here, specialization is the rule: divisions within laboratory medicine and pathology are staffed and directed by physicians (who may or may not be pathologists) dedicated by interest and training to their particular subspecialties.

The trend is toward subspecialization; even the community hospital plays a part in this trend. Recent advances in hematopathology, immunopathology, therapeutic drug

*Carter PM, Davison AJ, Wickings HI, et al.: Quality and quantity in chemical pathology. Lancet 2:1555-1557, 1974.

monitoring, and electronic data processing, to name only a few disciplines, make it increasingly difficult for the generalist to maintain anything more than a superficial acquaintance with all phases of laboratory medicine and pathology. Moreover, the growth of medical subspecialties and their spread to community hospitals create a demand for an equivalent degree of consultative expertise from within the clinical laboratory.

If laboratory medicine is to meet the challenge of the 1980s, pathologists and laboratory physicians must possess a depth of knowledge that can reasonably be achieved only by further specialization. The knowledge required is unique: it must encompass not only a sound understanding of analytical and instrumental principles, but an appreciation of clinical decision-making. Knowledge of this sort is not easily attained; clinical as well as laboratory experience will be required.

Progress in Clinical Pathology, Volume VIII, pays heed to the foregoing and attempts to lay a conceptual foundation for future challenge. The opening chapter by Dr. M. Desmond Burke examines the clinical decision-making process and the role of laboratory investigation in that process in an attempt to emphasize the ultimate aims of laboratory medicine. The chapters on preanalytical variance by Drs. Bernard E. Statland and Per Winkel and on reference values by Dr. Eugene K. Harris deal with subjects that are, in effect, prerequisites to appropriate interpretation of laboratory test results. The chapter by Drs. Beck, Meier, and Rawnsley deals with methods of data analysis that facilitate extraction of clinically relevant information from multiple pieces of information.

The clinical laboratory's achievements in technology have been truly outstanding and have provided clinical medicine with not only a more varied, but also a more reliable, data base in support of clinical diagnosis and management. Improvements in the control of analytical error have made clinicians more confident of test results. The introduction of automated methods of analysis has improved the laboratory's capability of responding rapidly to clinical needs and has led to the introduction of biochemical screening. Newer methods of analysis and technical innovation are now bringing an increasing number of biologically important constituents within analytical reach of the clinical laboratory. Finally, the advent of the computer and the introduction of microprocessors into assorted instruments promises to improve data communication—a necessary prerequisite to appropriate utilization of data. Despite the foregoing achievements, there is a continued need for newer analytical approaches and for reassessment of analytical goals. The foregoing are the topics of chapters by Drs. D. S. Young and R. P. Tracy and by Dr. Callum G. Fraser.

New developments in science and technology continue to influence the character of the various subspecialty areas within the clinical laboratory. This is particularly true of the blood bank: not too long ago, its sole function was the procurement, testing, and distribution of whole blood and plasma; now, the blood bank is responsible for processing a variety of blood products and for providing other services, e.g., tissue typing in support of organ transplantation. With the growth of modern immunohematology has come an increased awareness of transfusion hazards. This subject is reviewed by Dr. Herbert Polesky. Advances in clinical pharmacology and analytical technology make therapeutic drug monitoring one of the more rapidly growing areas in laboratory medicine. This subject is reviewed by Dr. Peter Jatlow. Chapters by Drs. Virgil F. Fairbanks and George G. Klee, Dr. Harry R. Hill, and Drs. Lance R. Peterson and Henry H. Balfour, Jr., all address new and important developments in other subspecialty areas.

Chemical dependency is now a matter of public concern. Dr. John J. Spikes, in a chapter entitled "Marihuana," examines the role of the laboratory in dealing with that substance—one whose use has reached widespread proportions among young people throughout the country.

Finally, Dr. Paul E. Strandjord considers a topic of increasing importance, namely, the organization and management of clinical laboratory departments. Modern management theory and experiences gleaned from industry, business, and other sectors of the community are brought to bear on the needs of laboratory medicine in the hospital and independent laboratory settings.

It is impossible in a volume of this nature to deal with anything other than a selected review of recent developments. The editors, therefore, have chosen those topics they consider most important to the field at the present time.

In conclusion we would like to acknowledge the important role played by Dr. Robert G. Martinek, Chief of the Laboratory Improvement Section of the Illinois Department of Public Health, in the development of volumes in *Progress in Clinical Pathology* over the past several years. He has been of great assistance in putting forward ideas, suggesting subjects, and providing general advice concerning the development of this series of progress reports. Dr. Mario Stefanini, the editor of this series, has provided direction and guidance to the editorial group of the University of Minnesota's Department of Laboratory Medicine and Pathology who have served as editors of this volume.

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M. Desmond Burke, M.D.

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Clinical Problem Solving and Laboratory Investigation: Contributions to Laboratory Medicine

INTRODUCTION

Over the past 25 years or so, laboratory testing has transformed the practice of medicine to such an extent that in 1978 12–14 billion dollars were spent on laboratory testing. Moreover, the volume of testing is said to be increasing at a rate of about 15 percent per year.[3] The laboratory's list of achievements is—by any standard—impressive: improved quality control; fast and accurate multichannel analyzers; and the development of new assay systems, e.g., competitive protein binding techniques, drug monitoring capabilities, and electronic data processing.[6,10]

There is, however, a growing concern that laboratory tests are, not only overused, but also misused.[6,100,103,104] In fact, medical technology in general and laboratory testing in particular are major contributors to the ever increasing costs of medical care.[89] Attempts to curtail those escalating costs have been the focus of a good deal of soul-searching in recent years. Suggested remedies in-

clude limiting the development and distribution of new technologies, eliminating old technologies, altering reimbursement practices to steer physicians away from technology intensive medical practices, creating a mechanism that might allow practicing physicians to share savings from a more efficient use of technology, and attempting to alter attitudes and value systems to the extent that "physicians would genuinely internalize the value of a low-technology style of practice."[89] Several spokesmen for the medical profession have shown something less than enthusiasm for any suggestion that medical technology be regulated.[69,89,100] As a corollary, creation of financial incentives and educational endeavors to alter behavior tend to be more acceptable.[6,69,89,100]

Financial incentives may be the answer.[89,100] There are, however, entrenched value systems that even financial rewards might not overcome. Modern medicine has its roots firmly planted in scientific determinism and has paid scant attention to its humanistic origins.[5,102] The latter suggests that "the proper concern of Man is Man";[102] the former is reductionist in its approach—an approach that undeniably is responsible for today's enormously successful scientific and technological achievements.[5] This 19th century view of science, inspired by Newtonian physics, sets today's standards for "scientific" medicine;[22] hence the view that finding the root cause of things supersedes other activities in clinical medicine. To this end, physicians often view laboratory investigation as they would a Newtonian physicist's crucial experiment; as a means of providing "objective data."[22] Clinical problem solving has suffered as a consequence.

Clinical decision making owes little to the scientific and technological advances which dominate today's practice of medicine. It remains outside the pale of "scientific" medicine; its legacy derives mainly from that of the French and British "pathoclinicians" of the 18th century.[41] In the mind of today's physician, laboratory investigation to uncover root causes or basic mechanisms is thus "scientific," while efforts to test the clinical decision making value of the same investigation is "unscientific." This, no doubt, provoked the writer of a recent *Lancet* editorial to comment, "The assessment of diagnostic methods belongs to the backwoods of clinical research."[37]

There is a good deal of evidence, from outside the traditional boundaries of "scientific" medicine, that clinical decision making is, in fact, scientific. Studies of human problem solving[90] and modern developments in the philosophy and psychology of science[12,88] support the notion that the "art" of medicine is scientific and the "scientific" component, as often practiced, is technological but unscientific.[23,86] It is ironic that the most reductionist of all scientists, quantum physicists, now reject scientific determinism for a probabilistic paradigm whereby the causes of things (diseases, events, values) may change with time or simply because they are investigated.[22]

The purpose of the foregoing preamble is twofold, to suggest: first, that the process of decision making is worthy enough to be considered scientific, a suggestion which if accepted might improve laboratory investigation habits;[6] and second, that there is already considerable evidence that analysis of the diagnostic process[68] and of laboratory investigation using the tools of other disciplines, e.g., information science,[32,51] process tracing techniques,[40,68] formal decision analysis,[110] and artificial intelligence[94] have already contributed to the laboratory's role in clinical problem solving and, no doubt, will contribute more in the future.

This review encompasses three areas: clinical problem solving, laboratory investigation, and the combination of the two—the laboratory role in clinical problem solving.

CLINICAL PROBLEM SOLVING

Clinical problem solving includes diagnosis and management. Diagnosis (the noun) is the intellectual end point of diagnosis (the verb). Thus, the diagnostic process leads to a diagnosis.

Diagnosis and Disease

The diagnostic end point is often called a disease. Names of diseases are merely convenient shorthand for long descriptions; thus there can be little general agreement on how to define "a disease."[23,24] Difficulties arise when a single diagnostic term is used to describe a syndrome,[131,132] e.g., diabetes mellitus: the term fails to distinguish mild glucose intolerance from overt disease; and, if used to describe the former, patients are placed at psychological and often financial risk.[67] Campbell et al. point out that the inappropriate use of diagnostic labels stems from the essentialist view that diseases are endowed with metaphysical reality. He, therefore, admonishes physicians to take