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Selected Methods for the Small Clinical Chemistry Laboratory Now in Spanish

Elvira Zavala de Serratos is the editor and Carlos Pérez Moreno the co-editor of a just-released authorized translation of this 1982 AACC publication, which in its Spanish version is entitled Métodos Selectos para el Pequeño Laboratorio de Química Clínica. These people, and the 12 persons who collaborated with them, are all to be congratulated. The 400-p product (paperbound) reflects great determination and diligence. The publisher is the Asociación Mexicana de Bioquímica Clínica, A.C., Mexico City.

AACC receives no royalty in this case; on the contrary, our officials were pleased to make this work more widely available in this way and were delighted that Sra. de Serratos would undertake (and accomplish) the task—as it turned out, under circumstances made even more difficult by interim shifts in the value of the peso.

Persons desiring a copy can obtain it at a very reasonable price ($40.00) by ordering directly from Sra. de Serratos. Her address:

Bahía de Todos Santos 49-3
11300 Mexico, D.F.

Government in Action

1/ At an Energy and Commerce Health Subcommittee hearing in February, Chairman Henry Waxman (D-CA) confronted Acting FDA Commissioner Mark Novitch, MD, on FDA’s inability to act quickly to implement the 1976 Medical Device Amendments to the Federal Food, Drug and Cosmetic Act, which required FDA to:
   a. Classify devices according to three different degrees of risk
   b. Review the safety and effectiveness of devices that were on the market before 1976
   c. Determine as a condition for market entry whether new devices are substantially equivalent to pre-1976 devices
   d. Develop performance standards for some devices
   e. Require manufacturers to develop and adhere to good manufacturing practices

   To date, FDA has not written one standard for the more than 1100 medical devices in that category.

2/ Cuts in public expenditure now being imposed by the Department of Education and Science are about to cause a major slowdown in the pace of medical research in Britain. The cash available this year for the Medical Research Council to distribute around the country to its own units and to university-run projects is being reduced by about £3 million, which amounts to about 3% of the MRC’s expenditure. . . . Nobody in Westminster or Whitehall expects the Government to relinquish such expenditure savings in the foreseeable future, any more than they expect Mrs. Thatcher to be converted from her religious faith in 0-level monetarism. . . . The result is that the MRC faces an extra £600 000 shortfall . . . Much of the burden of apportioning the cuts falls on the MRC’s secretary, Sir James Gowans, [who said]: “We hope to preserve the very best, since progress in research depends on that. But it will have a discouraging effect on morale, which is very important. It is essential for our organisation to be bombarded with other people’s good ideas. We want to keep up that flow. . . . We are not asking for tens of millions of pounds. Another £3 million would have made all the difference, and allowed us to fund some very good research projects.”

—Rodney Deitch, in Lancet, March 31, 1984, p 748

3/ . . . there were more than twice as many people (all categories) working in [Britain’s] NHS in mid-1982 than at the beginning of the ’60s. The NHS has been the largest single employer amongst all central Government departments since 1977, accounting for one in every two persons employed in all the centrally run services in the UK.

—Lancet, March 31, 1984, p 479

4/ Under current proposals, hospice services will be reimbursed by a certain amount per patient-day, according to four categories of level of care, and for a maximum of 210 days. At 210 days, reimbursement will cease, but the hospice program will not be allowed to discharge the patient. The Medicare hospice benefit requires physicians to certify that their patients have six months or less to live before the patients are considered candidates for hospice care.


5/ Every civilian agency with research money except the National Science Foundation and the Department of Transportation has undergone budget cuts, in real terms. Meanwhile, military research funding, in real terms, has increased by 53 percent. Research at NASA has been slashed by 61 percent, and at the Environmental Protection Agency it has been cut by almost half. A vast amount of promising research in medical sciences has either been canceled outright or put on hold. Because of these cutbacks, hundreds, perhaps thousands, of scientists have seen their careers disappear at the stroke of a pen.

The White House defends these cuts, saying that economic recovery is the most vital consideration. But that clearly is not the case, because what has taken place is a shift from the expense of basic science. Moreover, the Administration has enthusiastically embraced extremely questionable and costly ventures like the Clinch River breeder reactor.

—Science, 224, pp 1289, 13 April 1984.

The Future of Clinical Chemistry

The following excerpts are from a release by Ames Division of Miles Labs., Inc.:

Nearly 30% of physicians in this country conduct clinical laboratory tests in their offices. Laboratory chemistries alone are a billion dollar business . . . Of that, in-office chemistries account for about $50 million.

Medical equipment distributors across the country are reporting rapid growth in sales of in-office laboratory testing equipment (1). Some dealers estimate that within five years a major portion of laboratory testing will be conducted in physician offices.

A recent industry analysis (2) predicts that rapid introduction of immunodiagnostic and microbiological testing products will permanently change the way clinical tests are administered, while simultaneously increasing the number of tests performed. The market outlook calls for an average annual growth approaching 16% through the mid-1980s. Another industry analysis (3) concurred with that prediction.

Following are some of the recent actions by insurers and government agencies which are fueling the trend
toward in-office testing:

- Blue Cross member plans have developed a variety of rules and policies providing incentives for performing more procedures in-office.

- Late in 1982, the Health Care Financing Administration (HCFA) finalized regulations curbing the overhead costs hospital outpatient departments can charge Medicare for physicians' services on routine procedures that otherwise can be handled in-office. By equalizing the overhead costs paid to both types of providers, HCFA is encouraging provision of more services in-office.

- The new DRG regulations for Medicare which limit reimbursement for testing services provided in hospital have [sic] encouraged pre-admission screening of patients in the physicians office, where the service is fully reimbursed by Medicare.

And still another stimulus to in-office testing has been the so-called "doctor glut" and the resultant increasing competition for patients. Many physicians today are seeking ways to improve and expand their services—to make them more responsive to patient needs. The new in-office diagnostic technology gives them a tangible means of upgrading their services, by enabling them to provide patients conclusive laboratory results in minutes, during the office visit.

In-office diagnostic testing benefits the patient two ways—in convenience and, most important, in improved patient care. A patient whose physician conducts blood chemistries on site can have test results before they leave the doctor's office, whereas a patient whose physician sends out for tests may have to wait hours or even days for results.

There are several ways in which the physician benefits from in-office testing. Perhaps most important, in-office testing gives the physician greater diagnostic control. On-site laboratory testing virtually eliminates the need for time-consuming follow up telephone calls, which take on the average 14 minutes of staff and physician time per call (4). Furthermore, the physician gets all his or her lab results stat, without (their) costing the patient stat prices. Finally, in-office testing may provide a source of revenue for some practices, especially now that hospitals increasingly are looking to the physician to provide pre-admission testing services.

While there certainly is a fertile market for home testing products—results of most diagnostic tests in and of themselves do not provide a conclusive diagnosis. For that reason, the physician's office will continue to be the most cost-efficient site for diagnostic testing.

References

ABCC Certifies Eight
The following individuals have been newly certified in Clinical Chemistry by the American Board of Clinical Chemistry:

Paul Byvoet
Robert Foery
Patricia Anne Pleban
Vickie Mueller Thomas
Richard Thompson Tulley
James Hsin-Che Yuan

In addition, the following individuals have been newly certified in Toxicological Chemistry by the American Board of Clinical Chemistry:

Robert Melvin Johnson
Gerald Howard Sheys

Origin of Contributions to Clinical Chemistry
Of the 370 full papers and Notes published in this journal in 1983, 51% came to us from outside the U.S.

The largest number from a single country was 27, from the U.K. Other western European countries contributed a total of 94. Seventeen papers were from Canada, 20 from Japan, 22 from Australia/New Zealand, the rest from other countries throughout the world.

This percentage has gradually increased over the years, presumably reflecting the increasing international tone and authoritative voice of the journal. We like to think that the help we routinely offer to authors, especially those for whom English is a second language, played some role as well—as surely did the generous and conscientious constructive criticism offered by our Board of Editors and invited reviewers.

New Publications
An IFCC Education Committee manuscript, "A Basic Education and Training Framework for Medical Laboratory Technicians in Clinical Chemistry," has been released for publication.

New NCCLS Publications:
GP2-A, Clinical Laboratory Procedure Manuals; Approved Guideline.
16-A, Service of Clinical Laboratory Instruments; Approved Guideline.

Single copies of GP2-A, 16-A, and H15-A are available for $15 each plus $5 additional per copy for orders from outside the United States. Discounts are available for multiple copies. Payment is requested with orders. Please address communications to the National Committee for Clinical Laboratory Standards, 771 E. Lancaster Avenue, Villanova, PA 19085.

From Hoffmann-La Roche: Methods of Testing Combinations of Antimicrobial Agents (24 pp) and Antimicrobial Combination Therapy (30 pp). To receive copies of these two booklets, write Roche Laboratories, Division of Hoffmann-La Roche Inc., Nutley, NJ 07110.

Altruism: Capitalist vs Communist

From The New England Journal of Medicine, April 1984:

p 993: I've detected a change in [medical students'] conversational themes over the past 20 years. More materialism and less social awareness are apparent now.

—John M. Last, M.D.

P 930: I graduated from medical school in 1980 with a debt of $40,000. . . . I have loans from seven sources, at interest rates between 3 and 21 per cent. Thirty-five per cent of the debt ($14,000) is at an interest rate of 11.8 per cent or more. . . . my first loan payment became due during my third year of medical school, and another loan matured during the fourth year. Of course, I borrowed more money to meet those payments.

—Linda M. Frazier, M.D.

p 1061: . . . the intense, extreme, and indeed inhuman pressures of residency . . . do [nothing] to foster altruism and self-sacrifice in mature physicians.

—Robert L. Cohen

p 994: Why not establish a true medical Peace Corps composed of our highly trained but underemployed young specialists? Let's pay them what they are worth—say at least $60,000 per year—and send them off to the Third World to teach and give care. The cost of such a program would be next to nothing compared with our military-aid bills but could do inculcibly more than guns ever will for the
people of the world and for America's image.
—John M. Goldenring, M.D.

I have no problem with Dr. Goldenring's suggestion, but does the spirit of service he espouses really pervade American medicine?
—Robert G. Petersdorf, M.D.

p 995: [Fidel Castro] was very frank about having 1800 [Cuban] physicians in Africa. He quickly added that, for humanitarian reasons, the United States should be doing more in this area. He indicated that the basis for sending physicians was one of need. If the host country could pay for services, that was fine, but it was not the basic criterion for receiving such aid.
—Julius B. Richmond, M.D.

Meetings and Continuing Education

Synthetic Substrates in Hemostatic Testing: Current Status and Future Trends, July 27, 1984, a minisymposium offered by Stritch School of Medicine, Loyola University Medical Center. For information, write: Dr. J. Farreed, Department of Pathology, Loyola University Medical Center, 2160 S. First Avenue, Maywood, IL 60153 (telephone: 312-521-3256).

Review of Clinical Chemistry for Practicing Pathologists and Clinical Chemists. Summer Seminars: June 20–29, Stony Brook, NY: July 16–26, 1984, Snowmass, CO. Fall Seminar: October 18–25, San Diego, CA. Winter Seminar: December 6–15, Snowmass, CO. Registration Fee: $315 for practicing pathologists; $250 for residents. Ph.D. clinical chemists, others. Credit: Category I of the Physicians Recognition Award of the AMA and Category I ACCENT credit. Further information from Seymour Bakberman, M.D., Ph.D., Department of Pathology, East Carolina University School of Medicine, Greenville, NC 27834.

Personal Computers in the Clinical Laboratory, October 24–26, 1984, Duke University Medical Center, Durham, NC. Inquiries to: Michael Bishop, Medical Technology Program, Department of Hospital Laboratories, P.O. Box 2929, Duke University Medical Center, Durham, NC 27710.

Some Forthcoming Papers

Improved Detection of Oligoclonal IgG in Cerebrospinal Fluid by Isoelectric Focusing in Agarose, Double-Antibody Peroxidase Labeling, and Avidin–Biotin Amplification

Tomas Olsson, Vasiliakos Kostulas, and Hans Link

Discordant Inter-Kit Results in the Radioimmunoassay for Choriogonadotropin in Serum

Peter J. Rzasa, Vicente J. Caride, and Edward K. Prokop

Improved Liquid-Chromatographic Determination of Haloperidol in Plasma

Amiya K. Dhar and Henn Kutt

Affinity Chromatography Used in Distinguishing Alpha-Fetoprotein in Serum from Patients with Tumors of Hepatic Parenchyma and of Germ Cells

P. K. Buamah, C. Cornell, and A. W. Skillen

Differential Immunoaodorption Coupled with Rate Nephelometry for Estimation of DNA-Binding Immunoglobulins

Vincent A. DeBari, Joseph Nicoita, James F. Blaney, Edward F. Schultz, and Mark A. Needle

Two New Methods for Separating and Quantifying Bone and Liver Alkaline Phosphatase Isoenzymes in Plasma

Sidney B. Rosalki and A. Ying Foo

Free and Total Putrescine in Cerebrospinal Fluid Quantified by Reversed-Phase Liquid Chromatography

Richard L. Heideman, Kenneth B. Fickling, and Lynn J. Walker

Ligand Displacement Immunoassay: A Novel Enzyme Immunoassay Demonstrated for Measuring Theophylline in Serum

John A. Hinds, Christopher F. Pincombe, Robin K. Kanowski, Susan A. Day, June C. Sanderson, and Patrick Duffy

Specific Estimation of 24,25-Dihydroxyvitamin D in Plasma by Gas Chromatography—Mass Spectrometry

Ruth D. Coldwell, David J. H. Trafford, Hugh L. J. Makin, Michael J. Varley, and David N. Kirk

Electrothermal Atomic Absorption Spectrometric Determination of Aluminum in Serum with a New Technique for Protein Precipitation

Sue Brown, Roger L. Bertholf, Michael R. Wills, and John Savory

Automated Measurement of Amylase Isoenzymes with 4-Nitrophenylmaltoheptaoside as Substrate and Use of a Selective Amylase Inhibitor

Hiroaki Okabe, Yoshinori Uji, Keiko Netz, and Akio Noma

Theoretical Aspects of One-Point Calibration: Causes and Effects of Some Potential Errors, and Their Dependence on Concentration

G. J. Kemp

Familial Dysalbuminemic Hyperthyroxinemia: A Study of Four Probands and the Kindred of Three

Alfred J. Scottolini, Nadhipuram V. Bhagavan, Thelma Oshiro, and Linda Powers

A New Monoclonal-Antibody Two-Site Solid-Phase Immunoradiometric Assay for Human Thyrotropin Evaluated

A. Eugene Pekary and Jerome M. Herschman

Evaluation of the Aminostat-FLM Assay for Assessment of Fetal Lung Maturity

Gillian Lockitch, Bernd K. Wittmann, Shirley M. Mura, and Louise C. Hawkley

Two-Site Monoclonal Antibody Assays for Heart- and Brain-Type Creatine Kinase

Antony P. Jackson, Kenneth Siddle, and R. J. Thompson

Carboxyhemoglobin and Oxygen Affinity of Human Blood

Ermanna Rovida, Michela Niggeler, Stefano Carlone, and Michele Sa maja

Receptors, Antibodies, and Disease

Melvin Blecher

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