The Challenge of Laboratory Practice Research

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The discipline of laboratory medicine is undergoing rapid change as the entire health care system is being reshaped. Important trends that affect the laboratory include efforts at medical cost containment, a shift to managed care systems, consolidation of traditional organizations, technological advances, increased use of information systems, and changes in the workforce. The speed at which change is occurring and the profound nature of this change present a formidable challenge to those who work in laboratory medicine. To deal with the challenge, we must seek a better understanding of how to most effectively and efficiently conduct the practice of laboratory medicine in a new environment. Research in laboratory practice is one of the important tools to help increase this understanding

Trends in Laboratory Practice

To highlight the changes that have occurred in laboratory practice, it is of interest to compare some data from the early 20's period to that of the present.

A sentinel event occurred in June of 1923, when the House of Delegates of the American Medical Association began action resulting in a committee authorized to "undertake an investigation of clinical laboratories with a view to securing a responsible and proper supervision of and adequate equipment and facilities for this branch of medical work."[1] This committee made recommendations to legislate licensing and standards in order to assure competent personnel and suitable equipment, as well as for developing and implementing a survey of laboratory activities in the U.S. The standards were developed in what appears to be the first organized effort to put clinical laboratory standards in place. The survey was conducted, and the results were published in the *Journal of the American Medical Association* in April 1926.[1]

In this publication, it was noted that in 1925, approximately 74% of the 5342 laboratories identified by the survey were hospital-based, and the total cost of all tests performed was estimated to be $37 million. Among the non-hospital laboratories (approximately 1000) the survey identified a group of 314 that performed clinical work. This group, called "regular" commercial clinical laboratories, performed approximately 2.1 million tests annually. These "regular" clinical laboratories were primarily owned by individuals or partnerships.

It is significant that from 1925 to 1987, we, to some extent, lost track of what kinds of laboratories were doing testing in the U.S. and what kinds of testing were being done. When the Clinical Laboratory Improvement Amendments (CLIA) were passed in 1988, very little information was available on laboratories other than the small minority that had been regulated under the 1967

federal legislation.

The CLIA data base information now provides important demographic information about clinical laboratory testing in the U.S. In 1995, about 152,000 Health Care Financing Administration (HCFA) certificates were current. Since some are for multiple testing sites, the total number of laboratories was somewhat higher, approximately 160,000. Based on self-reported data from the HCFA registration process in 1992, the Centers for Disease Control and Prevention (CDC) has estimated that approximately 4.2 billion tests were performed in that year. From the same data source, about 60% of laboratories were reported to be in physician offices. These physician office laboratories (POLs) performed about 7% of the total volume of testing during this period. Hospital and independent laboratories comprised 9.6% of the total, but performed approximately 70% of the testing. Significantly, 31.6% of the laboratories classified themselves into other categories, such as renal dialysis units, hospices, nursing facilities, mobile units, and health fairs. Most of these laboratories were previously unregulated. Ownership of non-hospital laboratories, constituting 94% of the total, has shifted so that approximately 52% are now owned by corporations.

The kinds and numbers of clinical laboratory tests being performed have, of course, changed dramatically. Among the 314 non-hospital clinical laboratories surveyed in 1926, 40% of the tests were described as urine testing. Other tests, in decreasing order of frequency, included "Wasserman," blood, bacteriologic, sputum, and serologic. Approximately 3% were characterized as "blood chemistry." In 1992, the CDC CLIA baseline data from a statistical sample consisting of 6651 laboratories of all laboratory types showed wide variation in the number of kinds of tests performed. Most laboratories performed less than 10 kinds of tests, but many offered a considerable menu, with 59 laboratories having available more than 100 different tests.

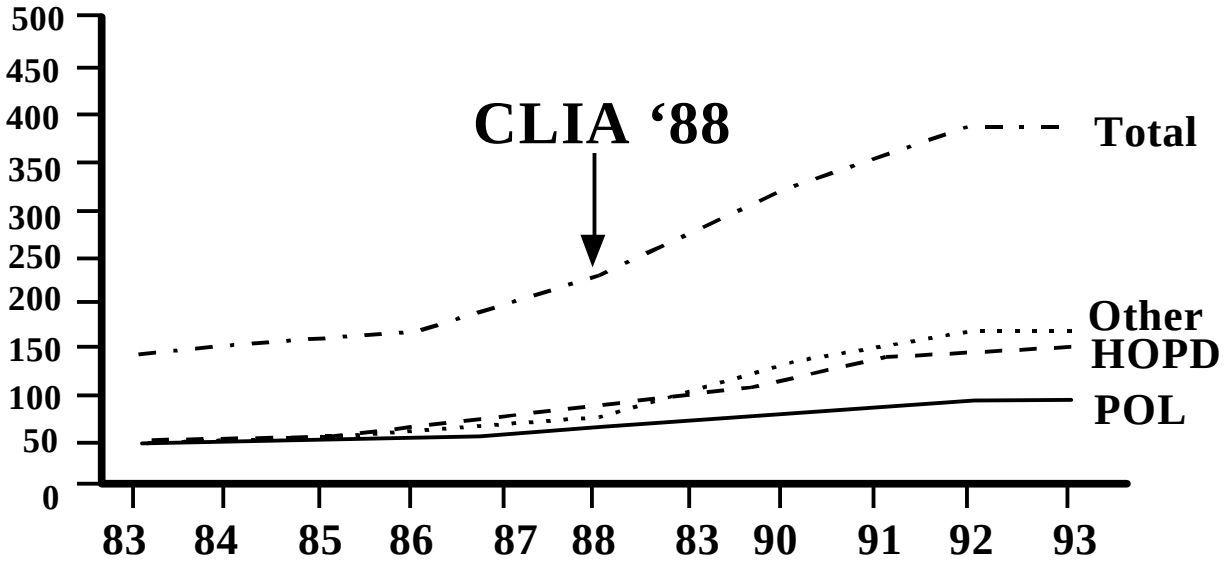
In examining trends in volume of testing, a recent study and subsequent report from the Office of the Inspector General studied the volume of Medicare-reimbursed laboratory testing beginning in 1983. A strong trend upward is apparent in all of the categories examined in this process. The final graph in this set is of particular interest, in that it shows a similar increase in tests performed per enrollee. (Figures 1-3)

Periods of Change

The trends for increases in numbers and kinds of tests, laboratories, and costs are associated with other changes in laboratory practice. For looking at these changes, and to place our current challenge in some historical perspective, it is perhaps useful to consider the development of clinical laboratory science in the following three phases:

- **The early years**, from the 1920s to the mid-1960s, were marked by the growth of the subspecialties of clinical pathology, the expansion of testing services, and an emphasis on analytical excellence. There was considerable promotion and growth of proficiency testing, and development of voluntary standards programs by professional organizations. Some states began regulating laboratory practice, and in 1967 the first statute providing Federal regulation was passed by Congress.

Medicare Reimbursed Laboratory Testing
Estimated Volume
(in millions)

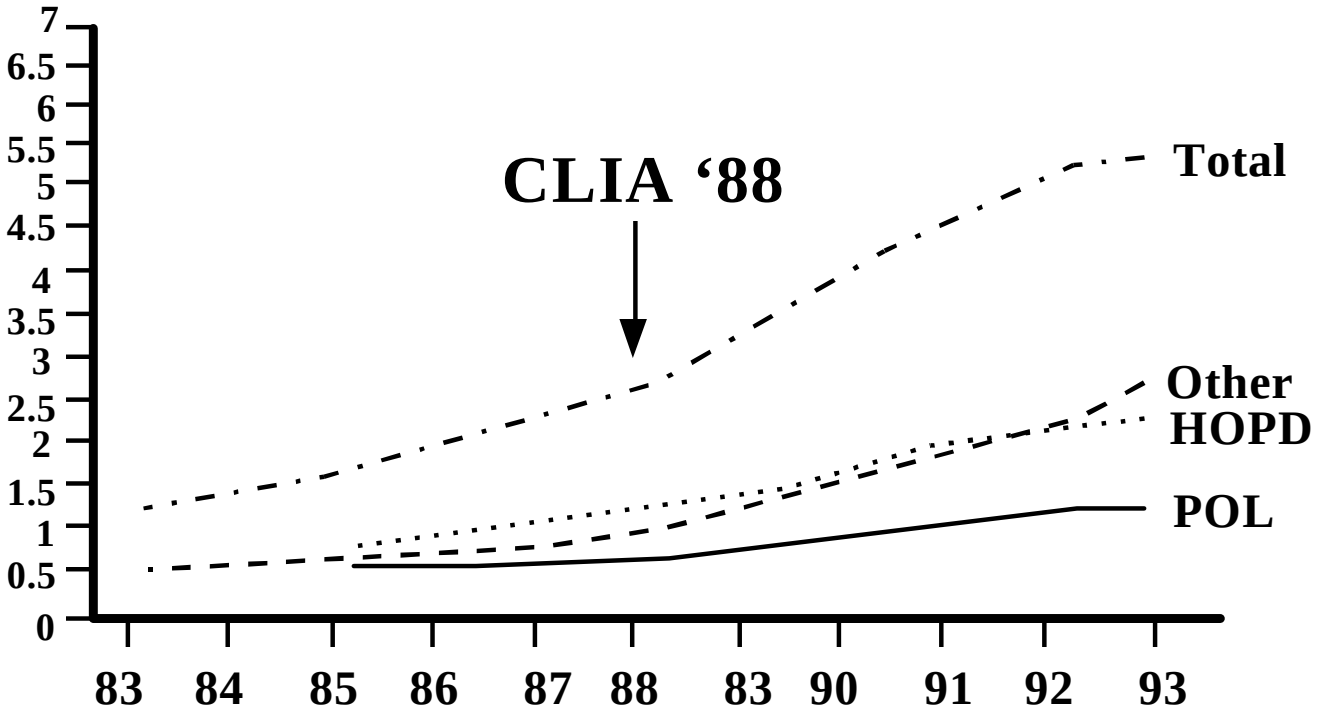


HOPD - hospital outpatient departments

Source: Office of the Inspector General

Figure 1

Estimated Expenditures
(in billions)



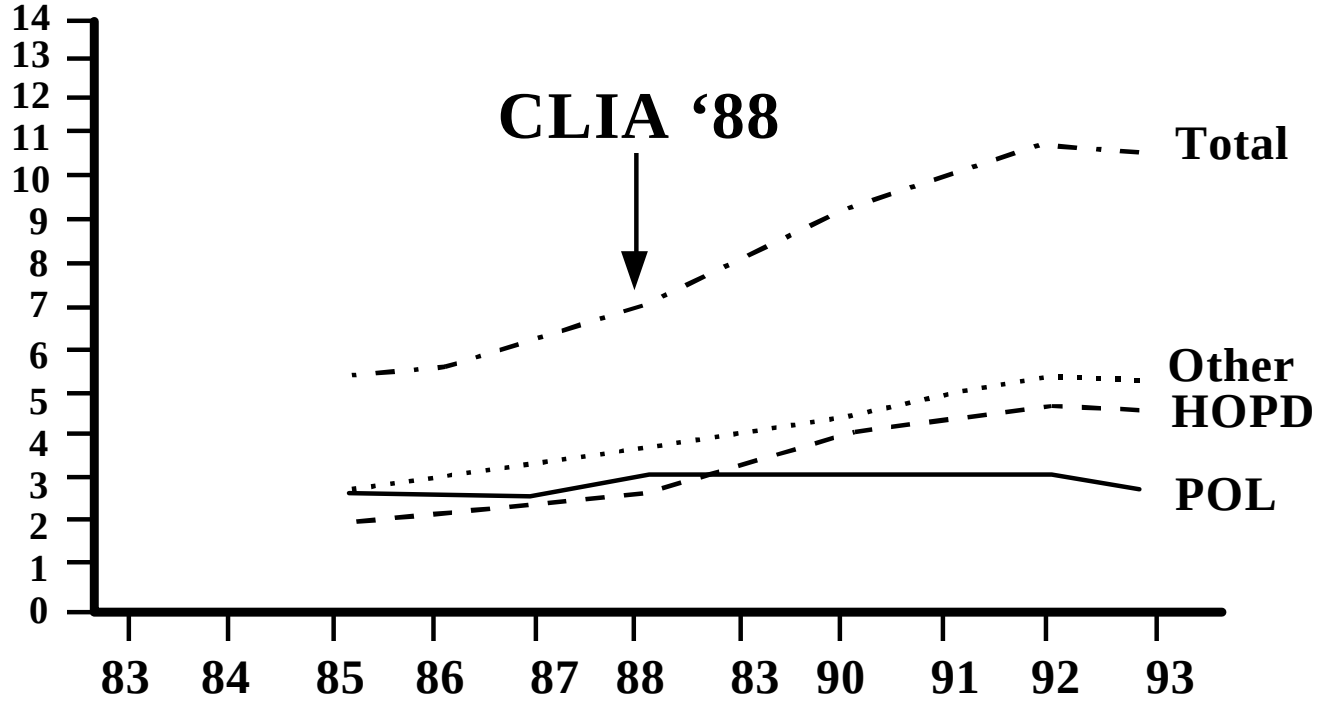
HOPD - hospital outpatient departments

Source: Office of the Inspector General

Figure 2

Figure 3

Estimated Number of Tests
per Medicare Enrollee



HOPD - hospital outpatient departments

Source: Office of the Inspector General

- **The development of the modern clinical laboratory** was well underway by the mid-1960s, characterized by an increasing number of types of tests as well as volume of testing. Automation of testing became an important element for all laboratories and heralded the beginning of the larger, regionalized or national laboratory. During this period, the CDC in 1984 began its Institutes on Critical Issues in Health Laboratory Practice. Through the Institutes, the laboratory community explored the concept of the total testing process, and focused attention on the need for laboratorians to respond to changes in medical practice and health care delivery. Increasing use of laboratory testing, growth of testing in non-traditional laboratories, and concerns about quality of laboratory testing were followed by the enactment of CLIA in 1988.

- **The post-CLIA 88** period has required adjustments to new laboratory standards, and has brought previously-unregulated laboratories into the overall effort to look at how best to assure quality of laboratory testing as we are driven by concerns about cost and effectiveness of care. We are challenged to evaluate the impact of the CLIA regulations, but are also dealing with a reorganizing health care industry, technological advances, and both consolidation and decentralization of laboratory services.

At the 1986 Laboratory Institute, predictions about possible major influences in laboratory medicine were made. Discussions about use of computers in care predicted increasing use in test selection, ordering, result validation, reporting, test interpretation, and treatment. These predictions have become a reality, and we are now looking at ways to use large data bases to help monitor demographics and potentially to look at quality of laboratory testing and clinical outcomes.

In regard to specimen collection and testing, participants in 1986 were expecting that the future would bring more self-collection of blood and other more difficult-to-obtain specimens, as well as an increase in home testing. Accurate timing was identified as becoming more important, and error-free sample labeling was thought to be achievable. There was a clear recognition of the effects of pre- and post-analytical processes on overall quality of testing. Growth in testing by untrained individuals with no professional oversight was mentioned as a concern.

Finally, there was considerable interest in new analytical approaches. Such things as using whole blood as a substrate, and an increase in using other body fluids such as urine and saliva were discussed. Non-reagent instrument systems, transcutaneous sampling and testing, miniaturization of test systems, non-culture microbiological measures, expansion of cell testing technology (surface markers), and new markers for disease and risk of disease were all thought to be important. There was also discussion of increasing use of DNA probes, antibody-based therapeutic drug monitoring, and computer assisted training and testing in anatomic pathology. Let's hope that we can have equal foresight in this 1995 Institute!

Based on a future vision of laboratory

practice as outlined above, 1986 Institute participants outlined a need for research in the following areas:

- Systems research studies of the total testing process
- Re-examination of workload productivity in the total testing process
- Studies of clinicians' behavior
- Development of computer databases for research
- Studies of new analytical devices and testing strategies
- Redefinition of the role of the future laboratory

Future Laboratory Practice and Research Needs

As we adapt to the changes that the post-CLIA period has brought about and as we look to the future, we need to direct our research activities appropriately. We have convened this 1995 Laboratory Institute to provide a forum for looking critically at current research activities and for developing new research strategies and ideas. We particularly seek the involvement of our clinical colleagues as we attempt to understand the future of laboratory practice. We need to promote existing programs that support analytical excellence, but must consider new areas for investigation, such as clinical outcomes, as well as new and innovative approaches to both answer questions and solve problems.

In this Institute, work groups will focus on selected topics and questions outlined in the prologue. As we start our deliberations, I would like to present some interesting data that relate to some of the workshop areas:

Proficiency Testing Enrollment in the United States

The increase in proficiency testing (PT) enrollment in the last 5 years, shown in Figure 4, almost certainly reflects a significant effect of CLIA requirements. One could also represent these data in dollars, because we are devoting considerable resources, both direct and indirect, to PT programs. Can we expect a concomitant increase in quality of laboratory testing? We are certainly going to be asked by those who pay the bills in this era of efforts at cost containment. Another thing to consider is that PT is the only element for which we are collecting data through the CLIA program that could be considered an outcome measurement. Is it a valid outcome measurement?

Laboratory Testing Personnel Employed at Different Testing Sites

Figure 5 reflects who performs laboratory tests, by indicating the percentage of hospital, independent, and physician office laboratories that utilize each of several professional categories of personnel. Laboratory personnel standards have varied considerably at different times in history. Significant changes have occurred in technology, and federal standards have been put in place that allow those without formal training in laboratory medicine to perform laboratory testing. What is likely to be the effect of these changes?

Outcome Measures of Laboratory Testing

All parts of the health care industry are being asked/required to look at the effects of

Proficiency Testing Enrollment

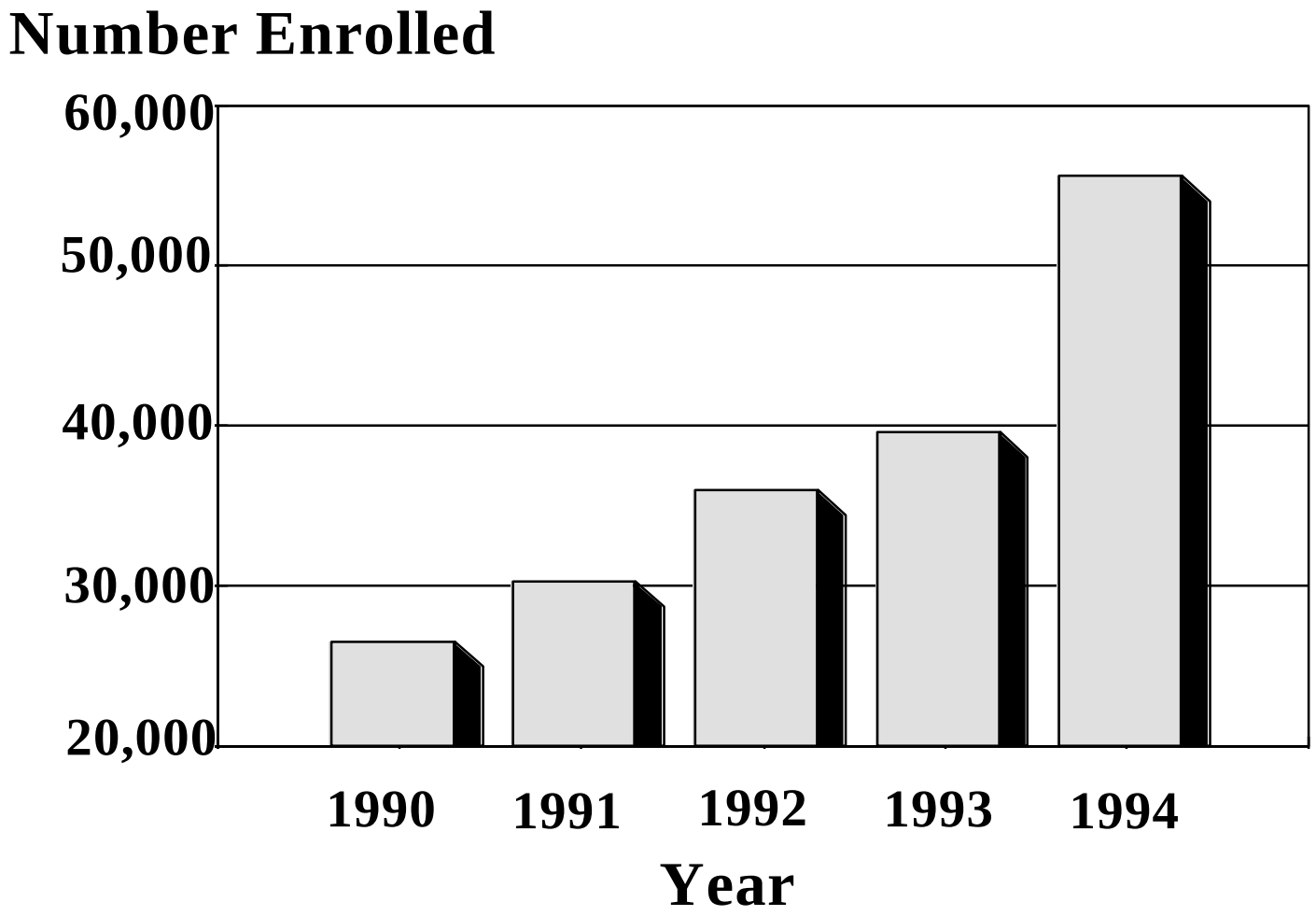


Figure 4

Source: CDC
Data not available from AAP, Pennsylvania, New Jersery, and Excel

Laboratory Testing Personnel Utilized in Different Testing Sites

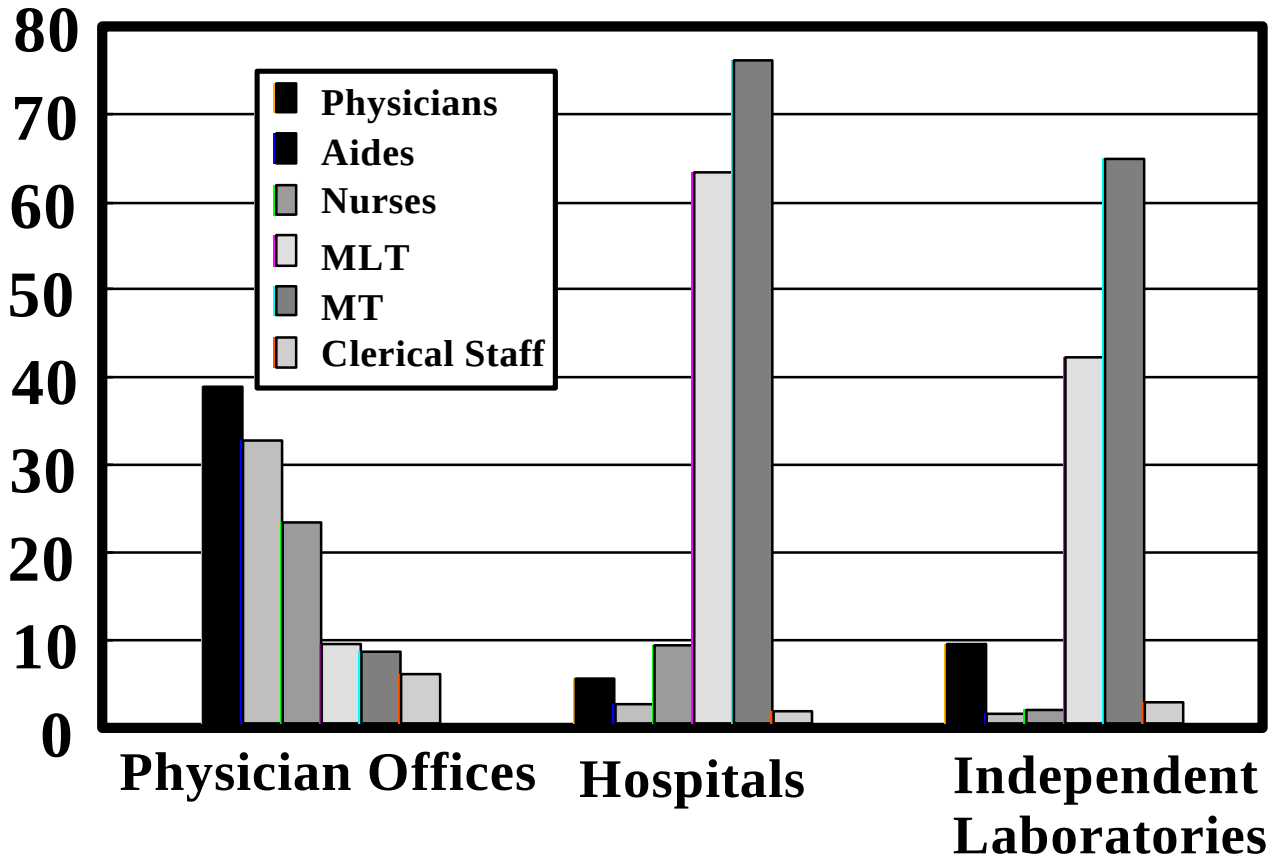


Figure 5

Source: CDC CLIA baseline data

what we do and to use outcome measures to help determine how best to use our increasingly limited resources. In direct services of health care delivery this has proven to be very challenging, and in laboratory medicine it is particularly difficult. We need well designed prospective studies in the area of outcome measurement. As we plan these studies, it is important to consider quality of care, patterns of care, cost of care, and allocation of resources, and we must do this in collaboration with those responsible for direct health care services. It is vital that we have close and collaborative interactions with our clinical colleagues.

Effect of Changes in Health Care Delivery Systems

Measuring the impact of change is a challenge that must be met. We are in a period of such profound change that we must be able to understand its effects and make appropriate adjustments. The effect of managed care on existing laboratory systems will be very significant. Most laboratorians are already working hard to appropriately deal with, and survive, this change. It is not likely to be easy. I have spoken with one laboratory manager who has 40% of testing, and 8% of income, coming from capitated arrangements with managed care institutions. In a show of hands among participants in a recent laboratory meeting, most, in a room of a few hundred people, indicated some business based on capitation, while some responded that all their testing is paid based on capitation. Figure 6 illustrates the rapid growth in managed care plans.

Other important changes include shifts in patterns of testing. Examples include the growth of POLs, home testing, and other point-of-care testing. We now actually have available the techniques - computer-based diagnostic modules, simple lab testing devices - to bypass the primary care part of health services delivery.

Better Research Methodology

Finally, we need to be innovative in looking for new ways to increase our knowledge and provide the information we need to deal with change. Increasingly available are data sets that are very large and that link laboratory and clinical data. We need to learn to use them to get the kind of information we need to help us in all these challenges. We need to assure that we, as laboratorians, have opportunities for input into developing data bases in the future.

We also need to look at ways to work with our clinical colleagues as we all seek the goal of improving the quality of health care. Opportunities for clinical collaboration to do practice-based research are increasing as primary care physicians form research networks. Figure 7 indicates the number and location of many of these primary care research-based networks.

A look to the future of laboratory medicine was the goal of a recent Delphi study using 107 laboratory experts from academia, clinical laboratories, government, and the laboratory manufacturing industry, and including consultants, laboratory directors, hospital administrators, managed care providers, laboratory managers, medical technologists, physicians with office laboratories, public health practitioners, and researchers. Round one of the Delphi survey was begun with a set of open-ended questions to which responses were solicited. In round two all responses were returned to the participants with a request that the 5 most important items be selected and scored from 1 to 5. Participants were also asked to strike out all items with which they strongly

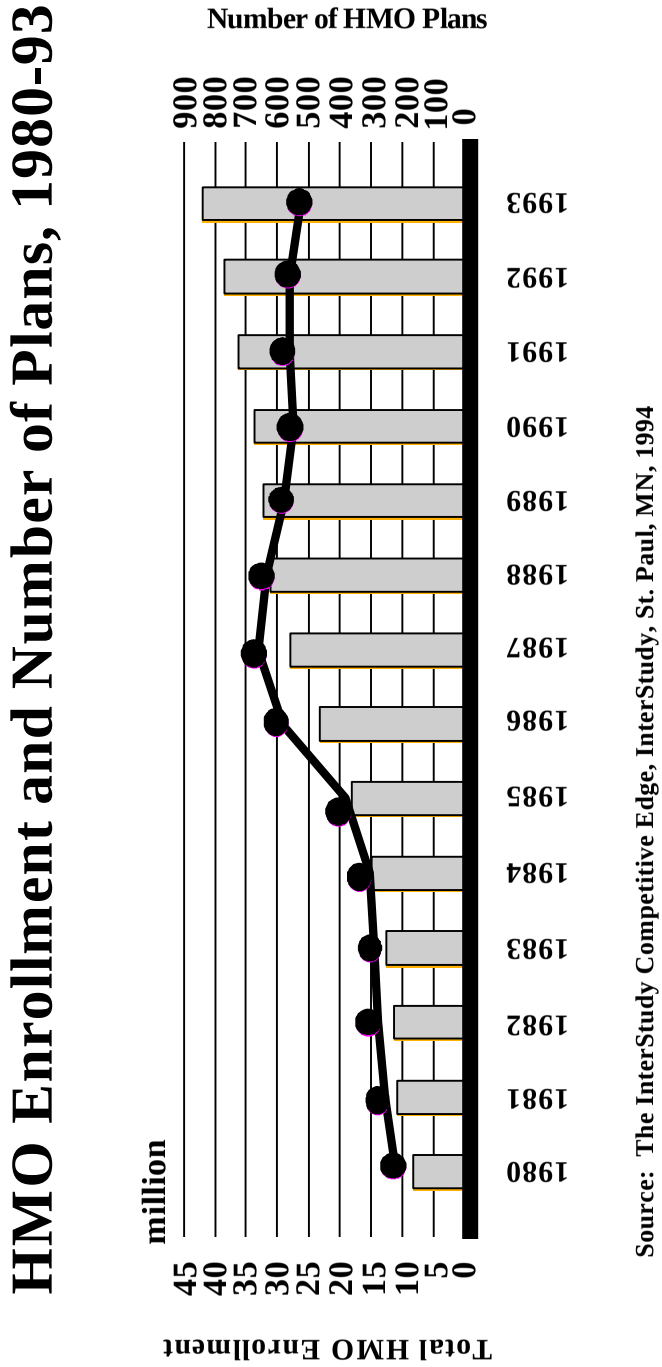

HMO Enrollment and Number of Plans, 1980-93
Number of HMO Plans
900
800
700
600
500
400
300
200
100
0
1993
1992
1991
1990
1989
1988
1987
1986
1985
1984
1983
1982
1981
1980
million
45
40
35
30
25
20
15
10
5
0
Total HMO Enrollment
Source: The InterStudy Competitive Edge, InterStudy, St. Paul, MN, 1994

Figure 6

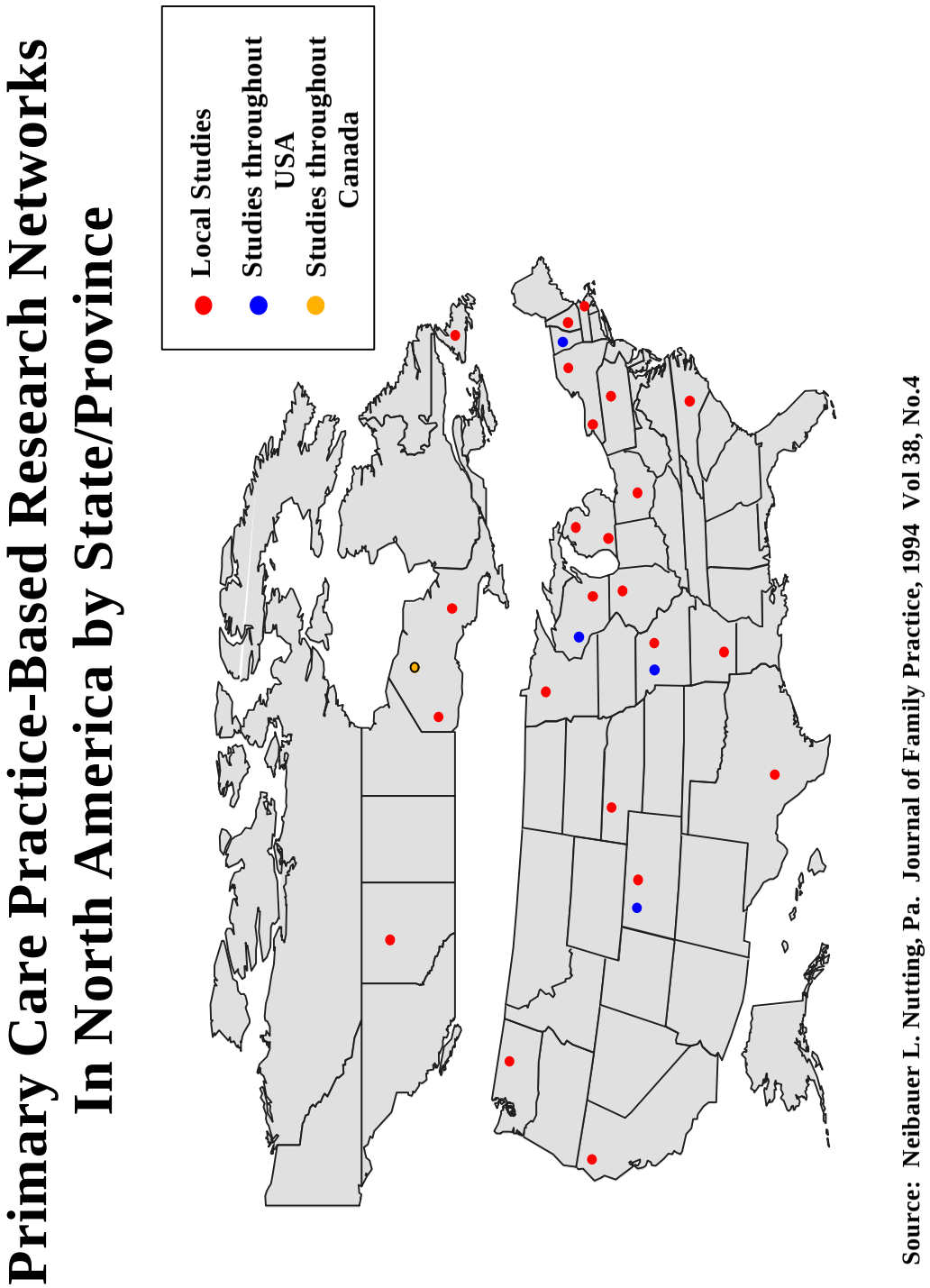

Primary Care Practice-Based Research Networks
In North America by State/Province
Local Studies
Studies throughout USA
Studies throughout Canada
Source: Neibauer L. Nutting, Pa. Journal of Family Practice, 1994 Vol 38, No.4

Figure 7

disagreed. Responses were ranked statistically, and it was noted that there was surprising convergence across categories of expertise. The results, with responses being indicated in descending order of frequency, are as follows:

Which forces of change will have the greatest impact on the nature and quality of clinical laboratory medicine in the next five years?

1. Cost containment
2. Medical informatics in health care
3. Shift to managed care
4. Laboratory automation and robotics
5. Industry consolidation
6. Changes in the work force

How will clinical laboratory testing and delivery of services change in the next five years?

1. There will be fewer laboratories, fewer skilled positions, and more automation.
2. "Mega"laboratories will provide the majority of services and take advantage of economies of scale.
3. Networks will be the norm.
4. Point-of-care testing will replace traditional laboratory systems.
5. The standard will be: lowest cost at the fastest turnaround time.
6. Clinical utility will displace current standards of acceptable accuracy.

What will be the impact of these changes on research in laboratory medicine?

1. Increased requirement for outcomes to prove medical efficacy
2. More directed, less basic research
3. Research and development will be industry-based, and focused on automation and molecular diagnosis
4. Profit-oriented test development

What will be the nature of clinical laboratory quality assurance?

1. Inter-departmental
2. Will include clinical pathways
3. Outcomes-based and patient-oriented
4. Expert/smart systems based
5. Include real time monitors
6. Integrated and seen as a process issue
7. Standardized through bench-marking with other laboratories

The results of this Delphi study give a vision of the future of laboratory practice from experienced experts from a wide variety of settings and are pertinent to our efforts in this Institute. Using this vision, and amplifying and expanding it from our own experiences and collective wisdom, we can begin the process of considering the Institute questions. In conclusion, to continue the extraordinary gains made in the quality of laboratory testing that has been seen in the last ten years, our research must extend from our vision for laboratory medicine. Through this Institute we hope to learn from the changes that have occurred and to attempt to understand what the future will bring.

Acknowledgments

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