Lab Practice Changes: Diagnostic Medicine by the 21st Century

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Abstract: The nature of product technology in diagnostic and therapeutic medicine is in the process of a dramatic change driven by both discovery and innovation in product technology, combined with fundamental changes in the worldwide macroeconomic environment and distribution system for health care products. Four major macroeconomic forces are driving change in the diagnostic medicine industry: The increasing cost of health care is the primary driver and the most important area of change. Also important are the changes in (#2) an aging population, (#3) the makeup and training of the patient population, and (#4) the explosion of new product technology. These four major macroeconomic forces, in turn, have stimulated five types of change in the health care system:

1. A shift in the paradigm
2. A major shift in patients' attitudes and expectations
3. A reshaping of the distribution channel
4. A modification of the industry's infrastructure
5. Technology change and innovation

The implications of these changes are significant for all providers of health care because they address the fundamental structure of the industry.

The presentation provides a background and perspective on these aforementioned areas of change, with the primary objective of describing the future course of diagnostic product technology and the laboratory environment that will be in place when these new products are brought to market. Three objectives will be satisfied:

To review the major macroeconomic forces that have already begun to reshape the health care industry and note the changes these trends demand from product development efforts;

To identify the major technology platforms in diagnostic medicine that could be brought to the marketplace over the next 5 to 10 years;

With this information as a backdrop, to describe the probable impact of these development efforts on the laboratory environment for diagnostic products.

The presentation will be based on series of independent investigations fielded by The Genesis Group during 1995 in preparation for the upcoming CDC conference, Frontiers in Laboratory Practice Research. Findings are based on interviews with senior industry executives and academic scientists, using a modified Delphi technique for forecasting. The analytical process used is essentially a straightforward commercial analysis of product development activity. This analysis is based on judgments by the industry executives and scientists.

The past ten years have been a period of unprecedented investment in research and development efforts linked to new technology platforms in diagnostic and therapeutic medicine. Billions of dollars have been channeled into a diverse range of innovations, from DNA amplification through gene therapy ind new vaccines. These general area of innovation can be grouped as follows:

- Diagnostics - More efficient and integrated means of determining diagnosis.
  - Diagnosis at earlier stage with more precise information
  - Diagnosis and monitoring of disease level (e.g., viral load) and therapy effectiveness
  - Enhanced specificity of analyte systems (e.g., serotyping/ identification)
  - Multi-analyte detection systems
  - Lower cost diagnostic processes

- Therapeutics - Broader array of therapeutic tools and applications with significantly enhanced specificity, which include:
  - New technology platforms ... e.g., gene therapy: 70 programs are in human clinical trials
  - Viable immunotherapy indications... alpha interferon. cytokine combinations
  - Monoclonal antibody (MAb) fragments finally work
  - Antibiotics used in ulcer management ... Biaxin with Prilosec
  - Vaccines for broader group of diseases ... melanoma
  - Entirely new classes of central nervous system (CNS) pharmaceuticals

Never before has such a diversified range of medical science investigations been fielded. Yet, the market does not yet fully reflect the benefits of these actions. The end product for most of these investigations remain many years from market introduction, but they ultimately will reshape the course of diagnostic medicine.

The purpose of this paper is to provide an overview of the scaffolding from which these areas of future product innovation in the field of diagnostic medicine will be constructed.

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This analysis is based on the judgments of the industry executives and scientists interviewed, and by Genesis Group

executives, regarding the commercial viability of these diagnostic product development efforts and their market timing. Our firm's hallmark is in melding the experience of the scientists and the corporate strategists to offer a point of view regarding the future course of product development in medical science. In essence, we focus on the strategic implications of technology activities and any current thinking on the future course of innovation in diagnostic medicine is reflected in this paper.

The Scaffolding For New Diagnostic Product Technology In Diagnostic Medicine

Five fundamental areas of future improvement in the technology platforms for diagnostic medicine have been identified. The primary areas of innovation will evolve in:

- Front-end specimen management technology
- Analyte selection, measurement and monitoring
- Instrumentation technology / automation and integration
- Back-end technology / information management
- In-Vivo ... Imaging and MAb fragments

Front-End/Specimen Management Technology Becomes More Sophisticated

Development activity in this area can be subsegmented by:

- Specimen selection...alternatives to tradition
- Specimen collection ... microminiature needles, patches
- Specimen preparation ... robot centrifugation
- Specimen handling... closed tube sampling devices
- Specimen transport... evacuated specimen tube via robots

Sample sources can be more flexible. Exhaled air with tracer is already under investigation for H. pylori / ulcer diagnosis. Saliva, urine, skin contact, tears etc. all offer substantial improvements in ease of use and convenience to both the clinician and the patient. Use of these specimens could very well become a reality in automated systems in the next 5 to 10 years.

Sampleless testing as a result of non-invasive instrumentation is evolving rapidly. Non-invasive infra-red, and optical instrumentations for glucose monitoring, for example, have already advanced to the prototype stage.

Sample collection devices such as contact biosensors for use in surface skin patches and in-dwelling systems may also be realized by the turn of the century.

One of the other more apparent innovations in specimen management technology revolves around robotic systems, which have become much more dependable. Automated sample management systems for transportation, centrifugation, and aliquotting are becoming commonplace. The rate of future innovation in robotics is expected to follow an even more rapid exponential path rather than a linear course due to the early stage of this product technology's life cycle. Another important innovation in this area involves membrane and related technology for serum and plasma preparation without centrifugation.

Analyte Selection, Measurement And Monitoring Include Broader Options

The investigative procedures that have been in development through the 1980s and 1990s (viral load monitoring, antibiotic susceptibility, specific cancer diagnostics / therapies, etc.) will be coming to the marketplace before the turn of the century, and this will become a marketplace in which, ultimately, breakthrough therapies such is antisense and gene therapies will be used. The most rapid advances are in evolving segments of molecular and immunodiagnostics medicine which will receive broader based acceptance. These include:

- Cellular analysis
- Infectious disease
- Cancer
- Genetic
- Immune function / competence testing
- Therapy monitoring

The most dramatic advances will come in cellular diagnostics as image analysis, and immunocytometry become more commonplace and as they become easier to use and accepted as valuable sources of diagnostic information for a wider range of disease states (e.g., cancer, infectious disease). Molecular / DNA probes methods will also evolve to a much more convenient process, and this technology platform will find broader utility in cancer, genetic disease and infectious disease.

New proteins/analytes will also emerge for use in chemistry and immunochemistry. The *breakthroughs associated with the Human Genome Project are potentially limitless.* Already, investments in this area are in the multibillion dollar range. Over 100 companies are actively developing product technology in this arena; some results are expected in this decade. Breakthroughs are generally expected to evolve in three phases:

- First phase ... single gene disorders, infectious disease
- Second phase ... cancer, diabetes
- Third phase ... multi-components, e.g., hypertension, autoimmune, psychiatric

To quote one of the many scientists interviewed during the process of preparing this and a similar paper for the College of American Pathologists, "Breakthroughs in this area should identify more analytes than you can shake a stick at." The impact of the Genome Project will be the addition of hundreds of possible diagnostic tests, including molecular probes, immunoassay and even other types of tests for diseases (sadly lacking in diagnostic medicine) for which no suitable diagnostic method currently exists. Dramatic advances in managing metabolic (osteoporosis), cardiovascular disease/atherosclerosis and central nervous system-related (e.g., Alzheimer proteins, Parkinson disease) conditions are also expected.

This influx of additional testing needs will impact laboratories already under pressure to reduce overall expenditures.

Instrumentation Technology Becomes More Simple, Portable, Flexible

In *instrumentation technology,* microchips / micromachines / microelectronics and, eventually, even nanotechnology will change the shape of instruments and leverage both existing as well as new diagnostic platforms:

- Biochemistry

- DNA/Molecular probes
- Immunoassay
- Serology
- Special testing, such as sperm motility

These advances will also be accompanied by dramatic advances in DNA probes, amplification technology and quantitative techniques in simple, easy-to-use lower cost instruments with built-in quality control systems. Technology will enhance speed, flexibility and communication systems. Biosensors will continue to evolve for use in: gases, simple chemistry, infectious diseases, immunoassays, etc. Viral load monitoring will allow us a quantitative assessment of the disease condition and a way for monitoring therapy.

Simple, low cost multi-analyte detection systems with quantitative multiplexing capabilities will:

- Become more commonplace ... from dozens to tens of thousands of reactions on a chip

- Evolve from chips with several technology platforms ... immunoassay, DNA probes, RNA probes, chemistries

Good examples of these development efforts are underway at firms like Affymax, Chemcore, Mosaic Technology, and Nanogen. One of the most significant events in this arena occurred in October 1994, when Affymax and its partner Molecular Dynamics received a $31.5 million grant from the U.S. Department of Commerce to develop miniaturized DNA diagnostic devices. The Affymax, Molecular Dynamics instrument concept measures fluorescence and uses capillary electrophoresis, a DNA sizing technology, to locate individual genes on a chromosome. Most of the grant money will be employed to miniaturize and microfabricate the entire sample preparation set of activities. This group is attempting to bring together all the front-end sample preparation activity required to isolate a DNA sample.

The implications of this development effort are dramatic. These firms are already collaborating with a consortium of researchers, including the California Institute of Technology, Stanford University, and the University of Washington, to develop a new generation of diagnostic devices that capitalize on the discoveries of the human genome and the developments in micromanufacturing. They all include DNA microchip technology and a chip reader.

Affymax has already developed the capability to put more than 10,000 DNA probes on a microchip. The end product will be a hand-held instrument aimed at dramatically reducing the cost--and increasing the speed and reliability--of DNA diagnostics for use in clinics, doctors' offices, and in hospitals.

Affymax and its consortium are not the only firms that have received substantial government grants for development activity in this area. In preparing this paper, we identified at least 12 other firms that have received some type of government support for developing the type of micromachinery necessary to bring these products to the market.

Another leading company in this area is Chemcore. This company has focused its activity on developing hand-held and benchtop diagnostic instruments integrating microchips and DNA amplification technology. Most of their product concept

stems from research and engineering efforts at the University of Pennsylvania.

In the near term, diagnostic instruments seem destined to become more portable, simple, and flexible. Over the longer term, even more dramatic advances are expected. To quote from one of the true futurists of our industry, Roger Cubicciotti of Biotechnology Research Associates, "It's only a matter of time before our technology becomes nearly as advanced as the microbes that invade us." There will ultimately come a time when the line between diagnostics and therapeutics becomes blurred. Medical devices will be capable of both sensing and repairing defects at the cellular and molecular level. They will do so by identifying structural and organizations disorders (much like management consultants), which will trigger pre--programmed repair instructions.

How will it be possible to cram all the benefits of an autoanalyzer and formulary into a single device? Actually, it will probably take several molecular machines to fix each damaged cell and billions to treat the patient. But they will be very, very small - knee-high to a bacteria. I can assure you that such molecular machines will evolve, just is the bugs they are designed to eradicate. And the bugs will fight back, through variation and selection. In the war between technology and disease, I cannot predict who will win in the end. But I can assure you that diagnostic tools will become smaller and drugs will become smarter until the two meld into one -- molecular machines doing hand-to-hand combat with molecular defects.

The inevitability of self-assembling, self-replicating medical devices is obvious from two simple premises:

1. Man's incessant drive to control matter at the molecular level, and

2. The reality that such complex molecular machines are physically possible, as amply evidenced by Mother Nature's own handiwork.

The only question is when.

Back-End Technology / Information Transfer Becomes More Convenient

Most of the innovation will be brought about through the electronic information superhighway. It will reshape information transfer ... e.g., remote imaging/monitoring ... home, physician office and provider centers for virtually all the patient management requirements. It will also form essential components for the many outcome investigations used to evaluate and direct the patient management practice.

Areas of impact will include computerized patient records, information storage / remote message, monitoring and communication systems associated with:

Post-testing data control
Result telemetry
Parallel processing data

Voice-activated recognition systems are already on the market that manage up to 35,000 words and can transcribe simple dictation at a rate of 70 words per minute. Innovation in this area will be used to transfer findings and information throughout the diagnostic process more efficiently. Both traditional ind new destinations (e.g., LIS/HIS, CHIN, etc.) will be targeted.

In Vivo ... Imaging And MAb Fragments Come Into Their Own

Full antibodies for use in both imaging and therapeutics have lagged the expectations of the diagnostic and therapeutic product development community for the past 10 years. *In vivo imaging with antibody fragments* however, will become a reality by the turn of the century. This became clear from a December 1994 worldwide antibody engineering conference in California which suggested the primary drawbacks of the fullantibodies for use in both imaging and therapeutics will be overcome by Single Chain Fv fragments (sFv). More specifically:

1. The new antibody fragments penetrate the target site more rapidly than current antibody methods ... rate of uptake is also faster.

2. Background noise (NSB) with these fragments has been substantially reduced

3. The immune response problems (e.g., HAMA) with placing foreign antibodies or antibody fragment imaging agents in the patient's body are no longer major obstacles in clinical development.

4. Convenient delivery is ultimately going to be brought to the marketplace.

Phase I/II investigations are reporting results in line with the animal studies. Based on findings to date, antibody fragments should also find increasing usage in both diagnostic and therapeutic medicine (cancer, infectious disease, etc.) by the turn of the century.

Implications For The Future Site Of Diagnostic Testing ... Alternate-Site / Point-Of-Care Diagnostics

The health economic measurement of outcomes, which examines cost vs. utility, will determine the rate of market acceptance of this new technology . Cost justification will obviously be a critical step in this process.

What are the implications of all these trends for the site of diagnostic testing? Clearly, diagnostic instrumentation is going through an important change. Smaller, lower cost instruments with built-in quality control systems and very broad menus are rapidly evolving. These instruments, which will be brought to the marketplace near the turn of the century, will undoubtedly find increasing utility in a wide range of applications within the alternate site environment.

There are at least six areas where these instruments could have some utility:

- In the emergency room or ambulance, they could be used for monitoring a wide range of problems, from drug overdose through risk markers for a heart attack.

- They could be used in cancer management for the convenient identification of risk profiles for oncogenes and concurrent evaluation of many cancer-associated proteins.

- In infectious disease, they could be used for viral load monitoring and measuring immune response to

disease.

- In the field of cardiovascular disease, they could be used for predictors of imminent heart attack.

- They would also have very practical utility in two additional areas: the measurement of blood gases and immune response.

The primary market acceptance issue revolves around the expected health economic measurement of the patient outcome when these new tests are employed. For example: Do they represent a substantial opportunity to improve patient management? Do they offer an opportunity to reduce operating costs? Do they improve the quality of information and recordkeeping? Do they allow the physician to more effectively and efficiently handle a wider range of patients? Do they reduce operating/labor costs?

If the health economic measurement of patient outcome is that the cost-to-benefit ratio is acceptable, then the market-acceptance process will follow. Over the very long term, this dynamic should drive an increase in the role of near-patient testing diagnostics. It won't replace centralized diagnostic testing, but 5 to 10% of all diagnostic tests should be in some form of point-of-care testing by the year 2000. After that, the market will continue to seek greater efficiency in the testing process, and point-of-care will compete head-on with centralized testing in a variety of instances for increasing market share.

Measuring the Impact of Change on Laboratory Testing

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Abstract: This presentation covered the issue of changing population characteristics as well as the changing nature of health problems. There was a discussion of the health delivery system, the advent of managed care and its impact upon the delivery of health services. The influence of managed care on the clinical laboratory industry and the public health laboratory was also addressed.

The transition that the health care industry underwent during the 1980's served to modify dramatically the mind set of those in health care, from one based on a philanthropic orientation to a highly competitive business orientation. Almost overnight the industry has become market driven and consumer oriented.

Changing Population Characteristics

For the first time in history, western societies contain significant older populations, with characteristics and health attributes different from any other populations that have ever existed. At the same time that life expectancy at birth was increasing, approximately 75.8 years (72.3 for males, 79.1 for females), the age structure was also being transformed (today 11% of the population is $\geq$ 65 years).

Changing Nature of Health Problems

The nature of health problems in industrialized societies has changed dramatically during the 20th Century. During the turn of the century, major health problems were acute conditions (i.e., caused by disease agents in the environment, rapid onset, all segments of populations were at equal risk, acute conditions were epitomized by the "killer" epidemic).

This century we have witnessed the disappearance of acute illness as the persuasive type of disorder and the emergence of the chronic condition, various conditions that are more frequently linked to lifestyle, heredity, and even psychological state; major example include arthritis, cancer, rheumatism, hypertension, and diabetes. Once chronic conditions become predominant, the composition of the population becomes a powerful predictor of both health status and health behavior. It is interesting to note that approximately 50% of all deaths that occurred in 1990[1] could be attributed to several significant external and nongenetic factors (Chart 1).

Health Reform

In addressing the health problems in our populations and evaluating the impact of change on lab testing we must focus our attention on the health care delivery system and its dramatic evolution with the advent of managed care and the restructuring of the system which has now become a strategic

Actual Causes of Death in the United States in 1990

Cause	Deaths: Estimated No.*	Deaths: Percentage of Total Deaths
Tobacco	400 000	19
Diet/Activity Patterns	300 000	14
Alcohol	100 000	5
Microbial Agents	90 000	4
Toxic Agents	60 000	3
Firearms	35 000	2
Sexual Behavior	30 000	1
Motor Vehicles	25 000	1
Illicit Use of Drugs	20 00	<1
Total	*1 060 000*	*50*

**Composite approximation drawn from studies that use different approaches to derive estimates, ranging from actual counts (e.g., firearms) to population attributable risk calculations (e.g., tobacco). Numbers over 100 000 rounded to the nearest 100 000; over 50 000, rounded to the nearest 10 000; below 50 000, rounded to the nearest 5 000.*
Source: J.M. McGinnis & W.H. Foege, JAMA, Nov. 10, 1993, Vol. 270, No. 18.

Chart 1. Actual cuases of death in the U.S. , 1990.

imperative.

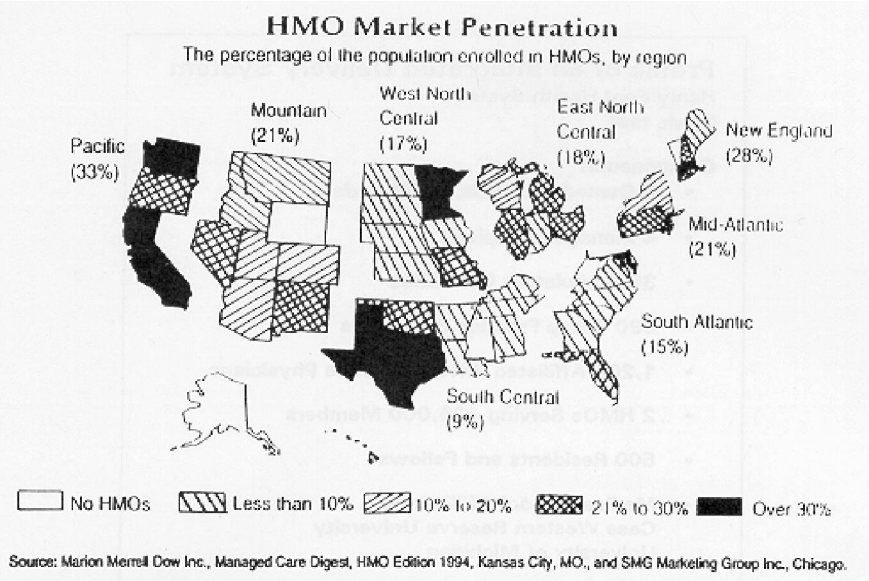
While it may have died on Capitol Hill in 1994, health reform is very much alive in individual states, and even accelerating in the private market place. The number of employees enrolled in managed care health, including PPOs, HMOs, and POS (Point of Service) jumped from 52% in 1993 to 63% in 1995. This is the biggest recorded increase in managed care enrollment during 9 years of surveys. The percentage of employees covered by traditional indemnity health plans, the most expensive option, fell to only 37% in 1995. This is the primary reason why medical inflation, measured at 4.9% in 1994, was cut almost in half since it hit a peak of 9.6% in 1990.[2]

Throughout the country employers and individual states have seized the initiative to not wait for government to solve their cost problems, through the use of managed care plans and cost management technique. Health plans are turning steadily to capitation to control their costs and share the risk with providers. As profit margins narrow and the price among providers becomes similar, the emphasis when selecting providers will be on quality.

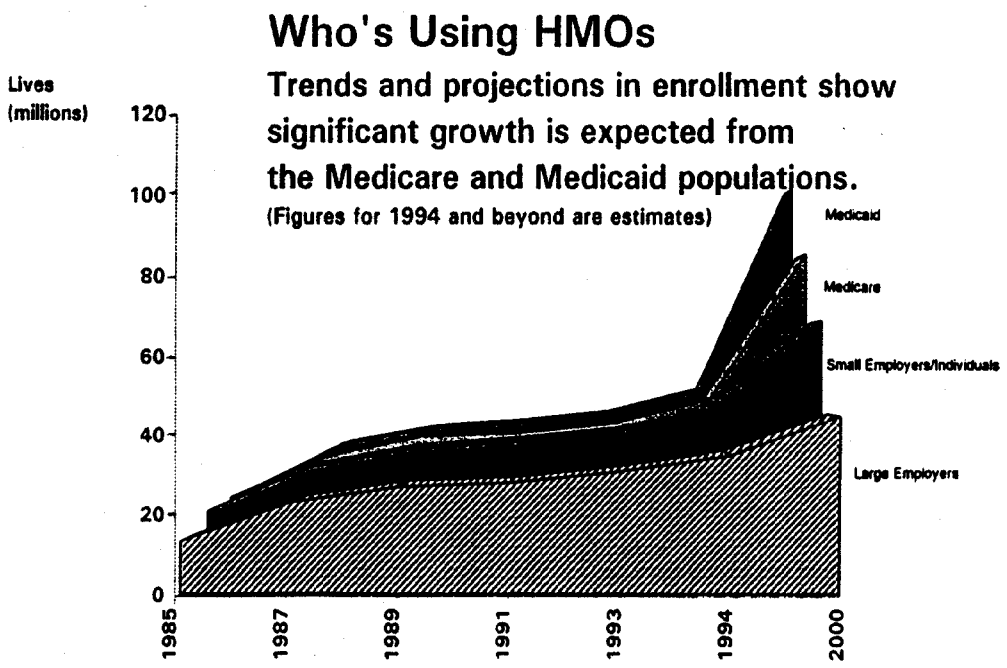
Graph 1 illustrates how HMOs have penetrated the market.

It is anticipated that the percentage of Medicare and Medicaid populations who utilize HMOs will grow significantly as illustrated in Graph 2.

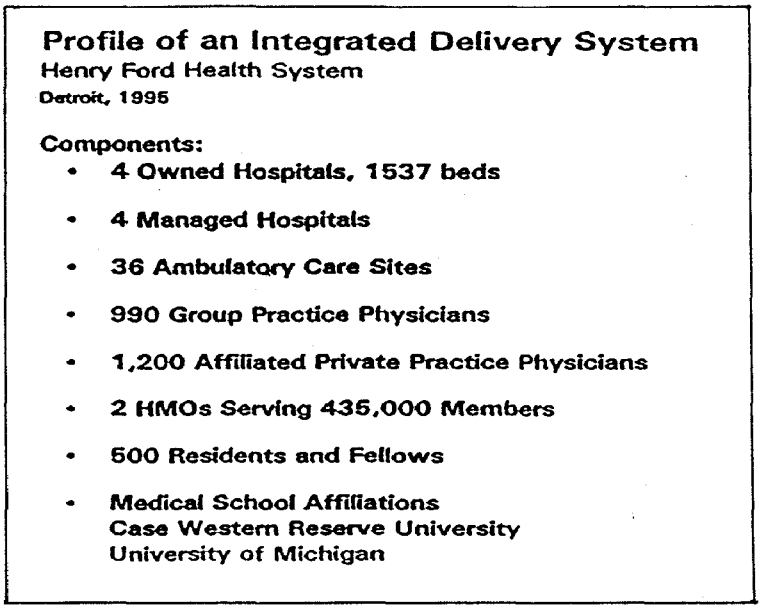
A major initiative by HMOs has been the promotion of clinical practice guidelines, developed (Graph 3) either internally, obtained from medical specially associations, or the AHCPR (Agency for Health Care Policy and Research), which has recently published a report translating their measure, and applications of those measure in quality of care standard setting, assessment, and improvement.[4]



Graph 1. HMO market penetration. The % of population enrolled in HMOs by region.



Graph 2. Use of HMOs by Medicare and Medicaid patients.



Graph 3. Henry Ford Health System (Detroit, 1995) as an example of an integrated delivery system.

The falling hospital occupancy rates (Chart 2)[5] and increasing outpatient revenues are forcing health care leaders to adopt new alternatives to outdated organizational models. Pressure has increased to consolidate, form networks, and right size delivery systems. More than 650 of some 6,500 of the nation's hospitals were involved in mergers or acquisitions in 1994; in comparison, only 71 hospital mergers were completed between 1990 and 1993 (source: American Hospital Association) The market's message to hospitals and their affiliates is simple: REDUCE PRICES AND PROVIDE BETTER SERVICE or risk going out of business. It is currently estimated that cost-containment systems spawned by managed care could force the closure of as many as 2,500 of nation's 6500 hospitals. In other words, "Holding on to old ways in this new and rapidly changing environment is asking for extinction."

The "urge to merge" has grown so strong as a survival strategy that 81% of 1200 acute care hospitals said their hospitals would not be free standing with in 5 years. To remain competitive and reduce costs, they indicated that they would join a network to share such services as laboratory facilities and information systems.

The march of managed care, new technologies, and alternative settings will prompt a 34% decrease in inpatient hospital days over the five years from 1994 to 1999, according to a new analysis by Sachs Groups. In the same period, discharges could decline by 26%, from 32.5 million to 24.2 million, the Sachs study suggests, while average length of stay could drop 11% from 6.1 for 5.5 days.[6]

The study also projected patterns from specific types of care:

Hospital Beds: The Declining Demand

An analysis of supply and demand in select Metropolitan markets in 1993 showed that only about half of current hospital beds will be needed by 2000

	Estimated Population (in millions)	Current Supply of Beds per 1000 people	Estimated demand for beds per 1000 people under current market conditions	Estimated demand for beds per 1000 people under managed care, year 2000
New York/Long Island	11.3	4.46	4.18	3.10
Los Angeles/Long Beach	9.1	2.90	1.93	1.54
Chicago	7.6	3.58	2.64	2.07
Boston/Nashua, NH	3.6	4.90	3.90	2.82
Philadelphia	5.0	3.46	2.96	2.42
Dallas/Fort Worth	4.3	2.78	1.73	1.47
Minneapolis/St. Paul	2.6	2.61	1.89	1.73
St. Louis	1.9	5.01	3.39	2.56
Miami/Fort Lauderdale	3.4	4.21	2.90	2.20
San Francisco	1.6	3.22	2.38	1.79

Source: Fox-Pitt, Kelton, New York, 1994.

Chart 2. 1993 analysis of the demand for hospital beds in selected metropolitan areas.

*Ambulatory facilities will eliminate many surgical inpatient days, with orthopedics dropping 38% to 10.5 million and general surgery down 150% to 13.9 million days.

*Use of birthing centers will increase, and many new mothers and healthy newborns will be in hospitals for stays averaging 12 hours that won't count as discharges. Thus, OB discharges will decline 30% from 3.9 million to 2.7 million, while length of stay will drop from 2.6 to 2.1 days.

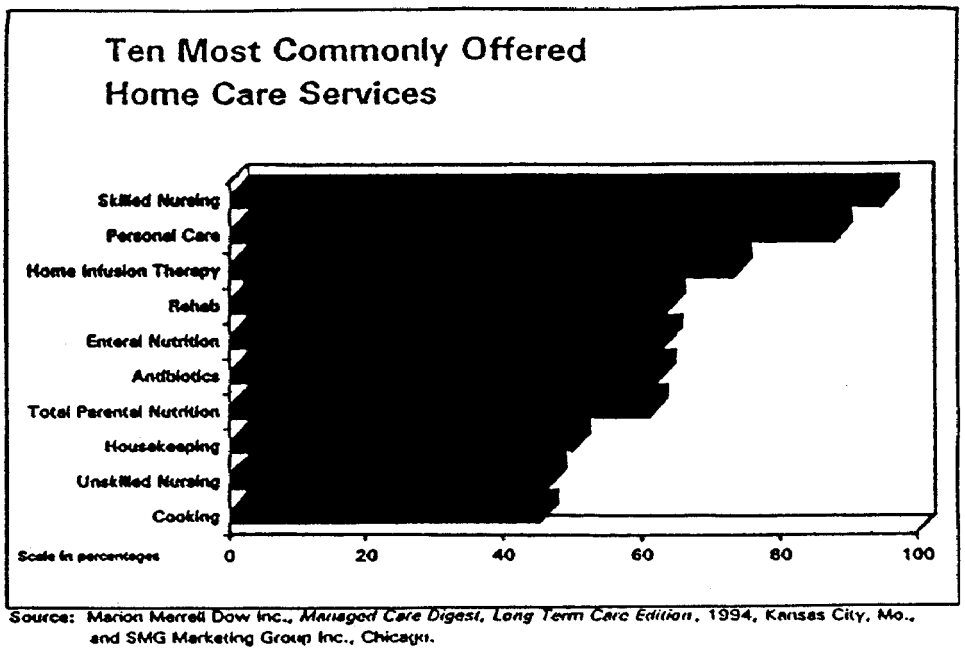
*Although there will be an 11% increase in HIV patient discharges from 121,000 to 134,000, length of stay will decline 25% from 12.2 to 9.2 days as use of hospices expands.

*Mental health care will be delivered more often in residential settings such as halfway houses, eliminating nearly a million psychiatric discharges for a decline of 59% and new total of 712,000. This is the biggest projected decline, in both percent and absolute numbers, for any type of care.

The trend toward integrated delivery systems is also occurring in response to employer and other health care buyer demands for lower health care costs, for health care that emphasizes prevention and wellness and for one-stop-shopping that guides patients to the most appropriate settings for medical care. A profile of an integrated delivery system is the Henry Ford Health System (Graph 3).[7]

Home Health Care

The most dramatic and fastest growing



Graph 4. Ten most commonly offered home care services.

segment of the health care industry combines cost-effective, high quality care and the comforts of home (Graph 4).[8]

The graying of America, efforts to control increasing medical costs, and advances in technology that make sophisticated patient care more mobile are all contributing to the growth of home health care.

According to the Health Care Financing Administration (HCFA), home health here grew by 23.8% in 1993 as compared with 7.8% for health care as a whole. Based on government figures for 1994, average home health charges per visit were $83, skilled nursing facilities charges per day were $284, and an average hospital stay was $1751 per day.

Impact of Change Upon Laboratory Testing

We will now focus on the kind of dramatic changes that are occurring right now in the laboratory (lab) industry. Two excellent publications that continue to monitor this are: The Medical Laboratory Observer and Dennis Weissman's Industry Report on Laboratories. The following discussion reviews the latest survey results that are published on the impact of Managed Care, particularly on the hospital labs and the changes that are occurring there.

There is no question that larger referral labs, primarily commercial labs, will soon begin processing the vast majority of tests. A survey that conducted of MLO's advisory panel--primarily laboratory managers--strongly believe that much of the work will eventually transfer out of the hospital and into the commercial setting. Managed Care obviously is putting a lot of pressure to cut costs. 44% of survey participants wonder what the impact is going to be upon the laboratory (Figure 1). 24% do believe that

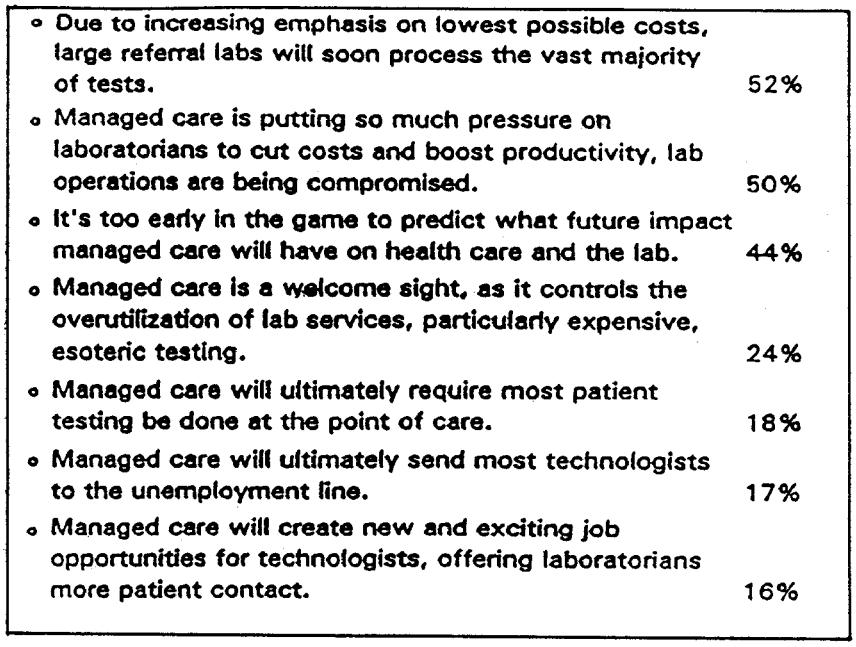


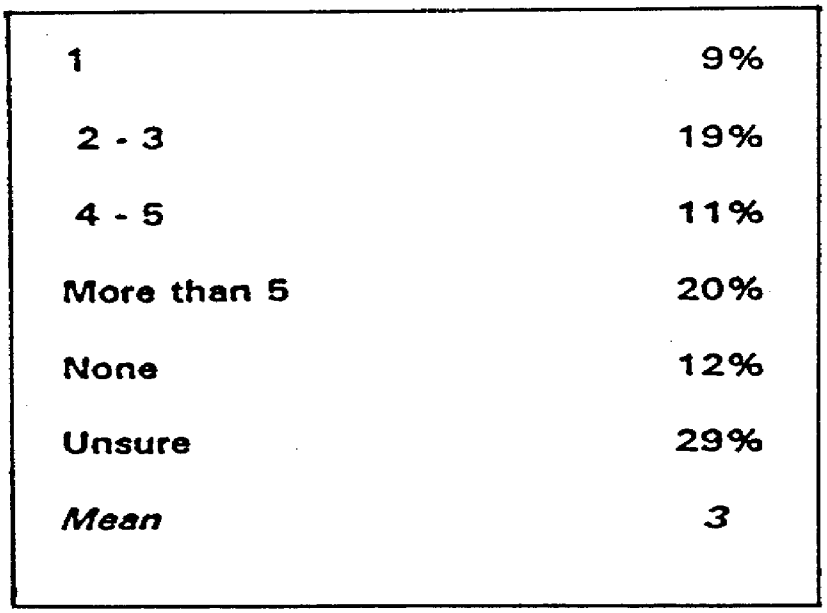
Figure 1. Managed Care's impact on the clinical laboratory. (Source: MLO, September, 1995)

Managed Care is a welcomed sight since it controls overuse of laboratory services--particularly expensive, esoteric tests. Ironically, when I began interacting with the private sector in our state, many of the people on our advisory council felt very strongly about this. It is time that there be a system that begins to focus on the over-utilization of laboratory testing.

Another evolving area, of course, is that Managed Care will ultimately require that patient care and patient testing be done at the point-of-care. Managed Care will ultimately send most technologists to the unemployment line. I can tell you in Washington during 1993-94 there was major downsizing of both hospital laboratories and certainly of the Public Health Laboratory. Whether many of these workers went to unemployment and then were recycled into other careers, we don't know, but Managed Care will definitely have impact upon your FTEs.

Other trends in the lab that have been a major outcome, so far, of Managed Care: Financial management is now paramount. It goes without saying that more lab workers are being cross-trained. Regulatory burdens are increasing. What impact is regulation having upon the laboratory? Right now a very anti-regulatory movement exists in the state of Washington. In fact legislation has been introduced with appropriate FTEs to re-examine the government regulation environment in our state. It wouldn't surprise me that, in fact, we may introduce some proposals about the way that we address licensure of clinical laboratories. We're the first state in the country with CLIA deemed status. Thus, we may also lead the way in the country in reforming regulation of laboratories.

More laboratorians are becoming involved in information management. I was



1	9%
2 - 3	19%
4 - 5	11%
More than 5	20%
None	12%
Unsure	29%
Mean	*3*

Figure 2. Number of Managed Care contracts that a hospital lab might have. (Source: MLO, September, 1995)

astonished to find that most laboratories in our state have a very good internal information management system but very few of them are connected to the outside world. We're going to try to do something to change that.

Figure 2 depicts the number of Managed Care contracts that a hospital laboratory might have; an average of about 3 Managed Care contracts.

Figure 3 indicates that stress among staffs is leading to the loss of valuable workers. I've seen this personally. For several friends who were in management positions, the stress has been overwhelming as we've gone through this transition and change. Personnel are being let go. Fewer QC and QA initiatives are being implemented as a result of Managed Care. This is certainly something that ought to be examined. Some of the survey respondents indicate that there are no negative effects. Others say that more testing errors are being made.

Laboratories are responding by acquiring instrumentation with greater versatility and increasing automation (figure 4). Cutback in total FTEs and major downsizing of laboratories particularly of management staff are common. There is a reduction of Medical Technologists which ultimately, of course, will extend Medical Laboratory Technicians. There is a lot more focus on self-directed work teams. Discontinuing certain tests and implementing bar code systems are improving efficiency.

Now this was something I thought was rather interesting (Figure 5). There's been a 35% introduction of practice guidelines for laboratory use. Panels and profiles have been reduced by 60%. About 40% of physicians and nurses are following stricter ordering protocol. More tests batched.

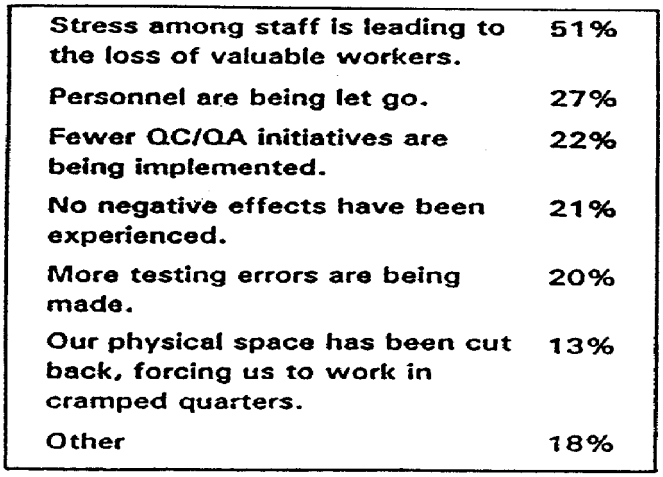


Figure 3. How Managed Care affects the laboratory. (Source: MLO, September, 1995)

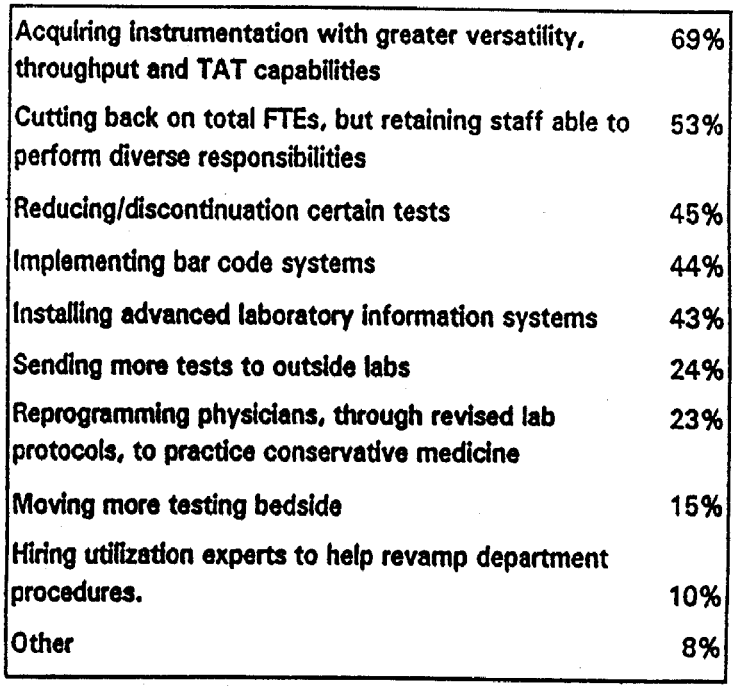


Figure 4. The laboratory's response to Managed Care pressures. (Source: MLO, September, 1995)

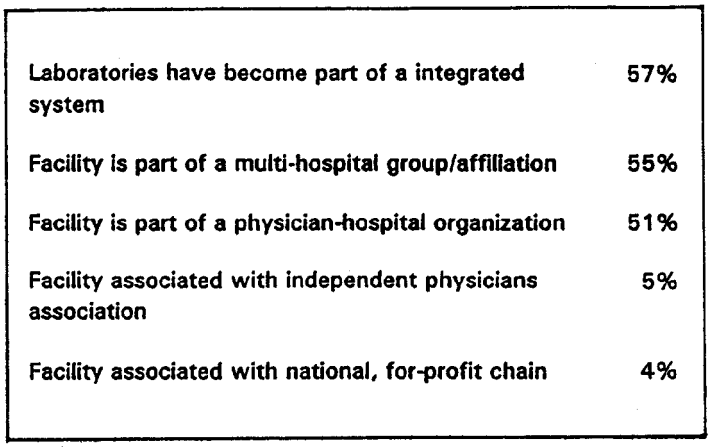


Figure 5. Integrated health care systems. (Source: MLO, September, 1995)

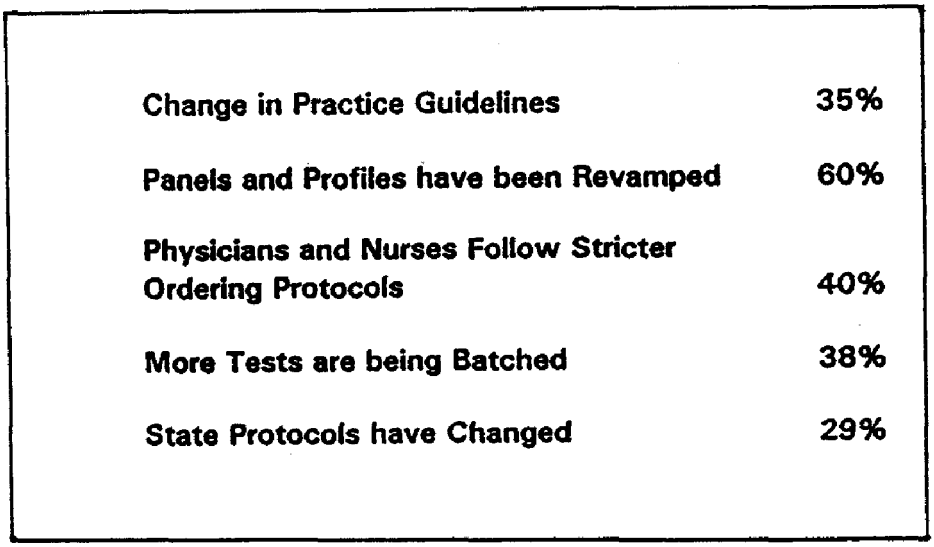


Figure 6. Impact on practice guidelines. (Source: MLO, September, 1995)

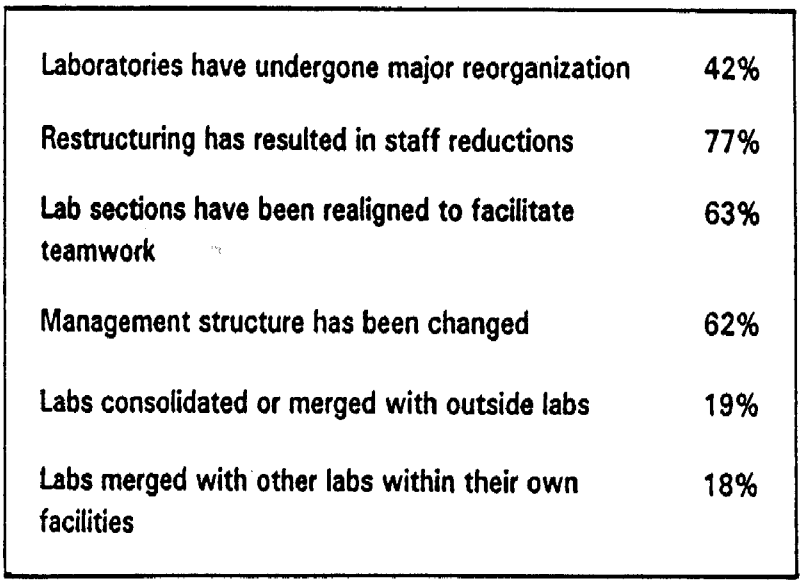


Figure 7. Reorganization of laboratories. (Source: MLO, September, 1995)

Dr. Steiner will cover the subject of networks and integration. 57% of laboratories have indicated that they're part of an integrated system (Figure 6). About 42% say that their laboratories have been re-organized and they're restructuring, which hasresulted in staff reductions (Figure 7). There was recently a consolidation of a major medical center in Seattle with Group Health which is one of the prominent HMOs in the country and which is going to impact substantially the pathology staff and at the administration level with a consolidation of responsibility.

So what are some of the anticipated changes that we might see in the future clinical laboratory system? (Figure 8)

Certainly the role of laboratory medicine will be expanded into promoting health, into prevention. There's going to be a major focus for the role of the clinical laboratory. The growth in home health care will promote home testing and increase direct public access to preventive and screening testing. A number of states have begun considering alternatives for the public to use and increase direct access to the clinical laboratory. This has certainly gone through some changes. Genetic testing obviously is going to be expanded. It is anticipated that by the year 2025 that all human ailments that have a genetic link will be identified and mapped in labs. Laboratories will also support preventive medicine.

Hospital and clinical labs will play a much more active role in the nation's disease surveillance, with an increase of laboratory reporting by electronic technology. This is something that we are extremely interested in Washington. We are in the process of implementing such a program. The first pilot project will be with Group Health which has about 500,000 members-- and once we evaluate that, this will move statewide.

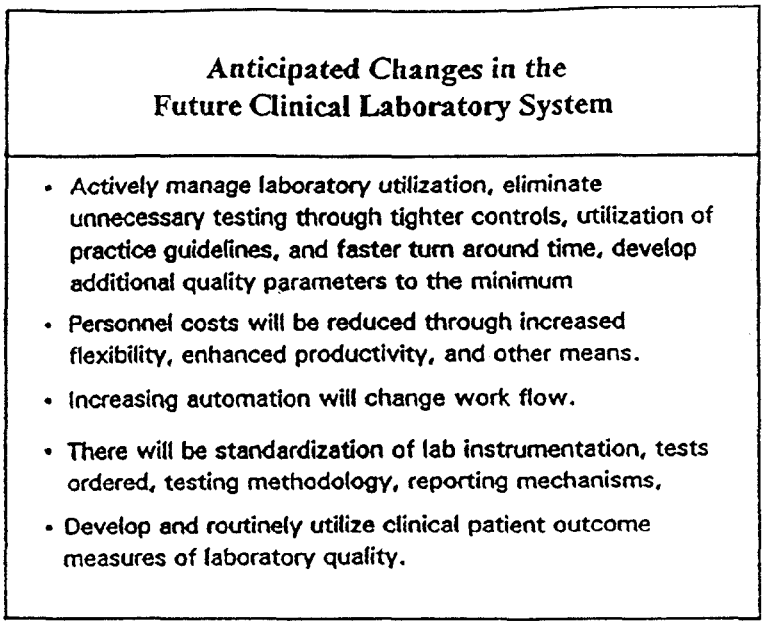


Figure 8. Anticipated changes in the future clinical laboratory system.

Obviously, once you develop an electronic network between hospital clinical labs and the public health system, then the potential for what can be accomplished is left to your imagination as to the type of electronic network you can develop in the future. Several states are now beginning to look at an integrated electronic communication infrastructure to examine utilization, patient outcomes, and so forth. This is obviously the future in laboratories as a producer of data. There's a tremendous amount of information in that data and obviously they're going to be a key component of any kind of state initiative around electronic networking.

It's going to be very important to focus on laboratory utilization, eliminating unnecessary testing through tighter control and utilizing practice guidelines. In your individual states you have a responsibility to step forward in a coalition and insure that the practice guidelines that are developed in your state are the ones that you want implemented. These are important issues of public policy, and our experience has been that when you bring together laboratory leadership from all areas, we in fact can develop this in a consensus process that can be very acceptable to the laboratory and physicians.

Personnel costs will be reduced with increased flexibility, mass productivity, automation.

Figure 9 is a comparative chart that was recently published by Dennis Weissman showing the trends in hospital and independent physician office lab which basically substantiates what the MLO survey results were: Hospital reduction in testing, industry consolidation, lower test utilization, independent labs more pressure to reduce costs, fewer total companies, obviously acquisition activity among the national and regional labs. In POLs there is less testing

Laboratory Industry Trends By Market Segment

Trend	Segment		
	Hospital	Independent	POL
Managed Care Growth	Reduction in routine and in-patient testing; more outreach and outsourcing in some institutions; push for cost-effectiveness and staff reductions	More pressure to reduce costs and prices; more capitation and contract bidding	Less POL testing overall and more limited menu of procedures
Industry Consolidation	Growth in vertical integration, regional systems and networks; more partnerships among hospitals and independents	Fewer total companies including small and medium-size labs; merger & acquisition activity among national and regional labs has peaked	Fewer solo POLs and more large group practice labs
Lower Test Utilization	Outpatients, outreach testing varies depending on market positioning; in-patient testing is down as length of stay decreases; when physician practices are purchased, more in-house work is captured	Capitated environment rewards less testing; Medicare utilization dropped by 8.9% in 1994; national labs have been forced by government to modify billing of panels; tougher local medical review oversight	Reduced test menu due to market & regulatory conditions; more waived procedures because of CLIA; Medicare spending dropped by 12% in 1994

Figure 9. Laboratory industry trends by market segment.
(Source: Lab Industry Report, Vol IV, no 4, July/August, 1995)

Impact of Managed Care Upon Public Health Laboratories

- Routine screening for STDs and HIV will transition to hospital/commercial laboratories
- Public health will focus their resources on disease surveillance, outbreak investigation, monitoring emerging infectious diseases
- Other priorities will be technology transfer, technical consultation and training, monitoring of quality assurance in hospital, commercial and physician laboratories
- Dissemination of information on laboratory methodology, molecular epidemiology data on public health significant microorganisms, laboratory practice guidelines on infectious diseases

Figure 10. Impact of Managed Care on public health laboratories.

going on.

What's going to be the impact on the Public Health Laboratory? I've already alluded to one area where I think we have a significant role in health reform/managed care, to bring people together, to help establish public policy. That is one of themandated roles of public health. There are other activities, however, where I see a dramatic change in public health as a result of Managed Care (Figure 10). HIV and STD screenings, for the most part, have been done through the public health system, whether it is local Health Departments/ Family Planning / Planned Parenthood/ Local Community Clinics. That population is beginning to move over to organizations that provide Managed Care. Some County Health Departments are not only going to stay in primary care, they are also going to extend it. They're looking at going into Managed Care themselves.

Public health is going to focus our resources on disease surveillance and outbreak investigation. A major task that we have is looking at emergent infectious diseases and not only having the laboratory capacity to focus on that, but again bringing the laboratory community together to see the role of hospital and the commercial laboratory around this issue.

Other priorities will be: technology transfer, technical consultation and training, monitoring of quality assurance in hospital, commercial, and physician laboratories. Very much a traditional role that we've always had. We've been asked to pick up that role in Washington because, again the training available for hospitals has really suffered because of lack of funding. And, of course, now we're being asked to extend our training to point-of-care testing and non-laboratorians that are doing that kind of testing.

Another major role you can anticipate from public health laboratories will be dissemination of material on laboratory methodology not only in microbiology, but throughout the clinical laboratory. We are beginning to become the depository for information on laboratory methodology and comparative studies that are ongoing within hospitals and commercial laboratories. Perhaps we could serve as a central point for disseminating that information through the laboratory.

There will be a major focus in the area of Molecular Epidemiology, the kind of data that we produce as well as the kind that is produced in the hospitals and clinical labs and re-emphasizing our role as a reference lab.

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Researching Change in Laboratory Systems

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Abstract: Technology, the expansion of managed care, and cuts in Medicare, Medicaid and other government programs to contain the deficit will all force rapid change on laboratory systems. To measure change, it is necessary to use the methods of time series analysis and to specify the dynamics of the process. Whether the terminology used is managed care, reengineering, or fiscal responsibility, the driving force will be money. Two primary indicators of system pressure and efficiency will be the ratios of revenue/cost and FTE/test.

The economic logic of managed care will remove cost-shifting and hence reduce the implicit subsidy of clinical research, so that new sources of dedicated funding must be found in an era of scarcity. The adverse outlook is somewhat mitigated by the fact that capitation is inherently population-based, and potentially more amenable to the methods of public health and health services research than traditional fee-for-service medical practice. Without billable revenues, laboratories will have to engage in cost-benefit research to demonstrate the value of their services. These studies will be similar to the emerging discipline of pharmacoeconomics. Indeed, the pharmacy may be an appropriate role model for the evolution of the laboratory. Pharmacists have shifted from manufacturing, earning money by custom production of pills, salves and solutions, to information services, providing demonstrated value in containing the cost of pharmaceuticals and improving the quality of bedside care. Laboratory research in 2010 is more likely to be collaborative so as to better meet the needs of clinicians, and because industry is apt to become a relatively larger source of funding. A changing structure will necessitate the development of new measures, new administrative data systems, and a new set of protections to defend scientific objectivity.

Change occurs over time. It forces us to use time series methods (rather than cross-sections). In addition to the standard questions (what is the dependent variable, intervening model, independent variables), change forces us to specify a time frame, and to make the model "dynamic" showing how, and how slowly, change occurs. Research is different in time series. The statistics are different, the "N" is different, confidence intervals are different. It becomes very apparent that how the questions are framed may be even more important than data quality in obtaining valid results.

What is our time frame? I would suggest it is on the order of 2 to 20 years; that is, after the next presidential election, but before all the candidates have died or finished writing their memoirs. The reference to politics was made to get a laugh, but also to point out that change occurs because someone wants it to happen, makes it happen, is willing to fight for it. And usually, at the bottom of much of that fighting, is money.

√	Technology
√	Managed Care
√	Funding Cuts
?	Location of Testing
?	Professional Boundaries
ø	Demography
ø	Economy

Table 1: Changing Factors: Definite, Maybe or Irrelevant

That is why I, although I am an economist and not a laboratorian, can claim some expertise in addressing this topic. The changes now occurring, whether called managed care, outcomes, re-engineering, or technological revolution, are being driven by money --and someone will have to be willing to put up some money if the necessary research on structural change in the laboratory is to be carried out.

What is changing? Let me briefly list several factors and suggest why some are, some maybe, and some are not relevant (Table 1). Topping my list are three changes that we can confidently predict will affect the laboratory over the next ten years: technology, managed care, and funding cuts. The effects of managed care are the central theme of this presentation. The succeeding sections are given over to building a conceptual model and developing measures to quantify effects. Let me briefly touch upon technology and funding cuts, since they are inextricably involved. How can we be so sure that there will be cuts in medical funding? Examine Figure 1. It is so obvious that U.S. Health care expenditures are out of line, with little evidence of effectiveness for the extra $400 billion spent, that even Congress can see that something is wrong. The deficit reduction is coming out of health care, kicking and screaming for sure, but coming none the less (N.B., "cuts" refer here as they do in most government to reductions in the rate of expenditure increase, although there will be some absolute dollar cuts as well). Technology has been addressed in a number earlier sessions, and there are many here in the audience more qualified to speak about how technological innovation is changing the laboratory. I would however, like to highlight several aspects of particular importance in my analysis--changes in the scale at which laboratory work takes place, reductions in the FTE manpower required per test, and advances in computing and telecommunications which have blurred the boundary between "laboratory testing" and "information services."

Changes in technology lead us to the middle or "maybe" category, where I have chosen two related trends for discussion: location of testing and professional boundaries. The "lab" as a dedicated space within a medical care facility is imploding, hollowed out by the centripetal forces of self testing and regional consolidation. The loss of an identified physical location may exacerbate the challenge to professional identity. Will laboratorians continue to exist when automation reduces the requirements for training in clinical chemistry, but increases the requirements for training in information systems? Will clinical physicians

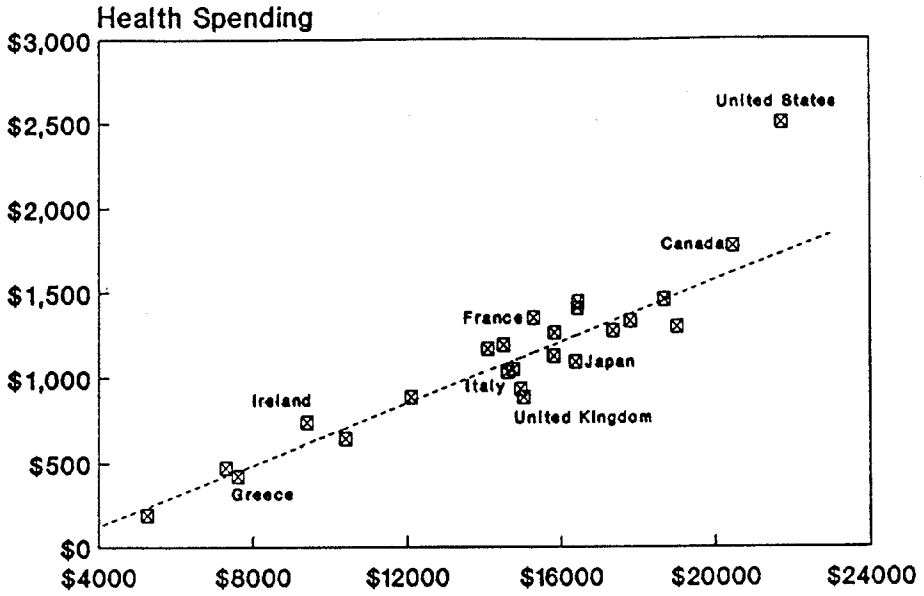

Figure 1. Cross-sectional analysis of 24 countries, 1990.

and insurance companies be users of laboratory services, or will they just take over those functions and any attendant funding?

At the bottom of the list are two factors which are frequently talked about, but which will not have a significant effect: demography and the economy. For all that has been written about the aging of America, the fact is that little aging will take place between now and the year 2020, and furthermore that the dramatic increase in aging around the world has had negligible impact on funding, manpower or other aspects of medical care systems. In brief, aging is a non-issue. The economy is clearly important, but, barring catastrophe, will grow and fluctuate pretty much as it has in the past. It will affect the situations of particular laboratories (sorry, California) but not the system as a whole. There is adequate growth in GDP to fund some expansion and refinement of services, but nowhere near enough money to wash away all of the problems caused by 20 years of excessive health care spending and avoid change.

Managed Care and Laboratory Billing

As "Managed Care" expands and mutates, it is sometimes difficult to determine exactly what is meant by the term. There are two elements which are central: "management"--the active intervention of a manager between the payer and the provider in the traditional third party relationship. Sometimes this management role may be internalized by the provider, as it is in a physician gatekeeper, it may be an entirely independent firm that does nothing but manage, as is the case for most commercial HMO's, it may even be a piece of software like "Claimcheck" residing within the computers of a financial system and putting out denials whenever it discovers an undocumented variance. The other fundamental element of managed care is payment by capitation, so many $ per member per month, rather than payment per test or per case. While capitation is still relatively rare for laboratory services, it is

1) Do not pay for cost-shifted overhead.

2) Select patients and providers that are manageable and low cost.

3) Change provider incentives to reduce utilization of limited effectiveness (or where elimination would not be noticed).

-- *NOT* keeping patients healthy (provides social, not corporate, gains).

Table 2: The economic logic of Managed Care

increasing. More importantly, capitation is removing the revenue stream from hospital and outpatient billing. Inpatient laboratory billing grew up as a form of "cost shifting." Early hospitals charged an inclusive per diem that covered nursing, medication, lab, and all other services. The lack of identified payment was problematic for clinical pathology, and in particular, for autopsies (it has always been difficult to claim that a patient benefitted from and should pay for a post-mortem procedure). Billing for laboratory tests was an effective way of subsidizing the necessary scientific services which were important for quality medical care, but not to a specific patient. Indeed, laboratory billing was too good of a way to raise money to be limited to pathology alone, and soon was being used to subsidize all sorts of activities from basic science research to charity and revenue shortfalls in the maternity clinic. Over time, the laboratory became the quintessential cost-shifting engine, transferring money from a place it was easy to get so as help out in places, like emergency rooms, where it was hard to get.

The logic of managed care is to remove cost shifting. By paying only what for what the patient needs, and avoiding the cost of autopsies, research, indigent care, etc., the managed care company is able to provide comprehensive services at much lower cost than standard indemnity insurance which has all of the cost-shifted overhead built in. To assess the potential impact of managed care on a department, the single most important measure is the amount of cost-shift overhead it is carrying under fee-for-service, more precisely, the "Revenue/Cost Ratio." Because this ratio is so high in the laboratory, they are especially vulnerable. For years, the excess revenues generated in the laboratory have protected it from cost pressures and management discipline. Those years of easy living not only allowed inefficiencies to creep in, but they also insulated the lab from the demands for accountability which other services faced. Laboratorians have not been good advocates for the value of the information they produce. Until now, they did not have to be. When millions of dollars are coming in and the overflow is being handed out to cover other departments, why work hard at slimming down, or at selling?

Quite simply, the days of easy money are over. Note, however, that we are in a period of transition where the revenues from fee-for-service billing still exceed the revenues from capitation, and will continue to do so until managed care penetration exceeds 75%.

Fee-for-service with high charge/cost ratios is so lucrative that only in a very advanced managed care environment--beyond Minneapolis and San Francisco even, does it make sense to align the laboratory with the long run incentives capitation.

In contrast to fee-for-service, **capitation is inherently population based** There is a clinical logic commensurate with the economic incentives listed above, and one that is much closer to the traditional perspective of public health and health services research than of solo clinical practice. Quality is defined in terms of expected averages, rather than individual procedures or provider credentials.

Outcomes Research

Capitation, being based on population averages, is much more amenable to the perspective of outcomes research. Yet contract for outcomes is not possible with current methods. Purchasing by "added life years" or "percentage restored function" may be routine by the end of the next century, but not within the 10 to 20 year time frame examined here. (In this regard it is worth noting that the federal HMO act was passed in 1973, but that managed care is only beginning to impact laboratory practice some 20 years later.) Outcomes research will require a similarly lengthy development period). Another problem with the idea of contracting for outcomes is that differences in the quantity and quality of medical care accounts for only a small percentage (10 to 20%) of the variation in health status. The acute medical model of discrete illness, with a well defined treatable diagnosis whose management can be made more efficient through refinement of protocols or "clinical pathways," may be applicable to as much as 80% of the population, but to only 20% of the cost. Alzheimer's disease, AIDS, crack babies, social pathology, mental illness and other "exceptions" take the great majority of the dollars. These social disorders and the massive cross-subsidy of the disabled ill by wage earners may be the issue which blunts (or sharpens) the penetration of managed care. In the year 2005, the dominant revenue streams will come from **contracting by capitation, but not by outcomes**

The Pharmacy as A Model for Laboratory System Change

Two challenges which threaten the viability of laboratories are 1)automation, which may reduce the numbers and presence of the profession below a sustainable level, and 2) an inability to defend the value of their work in an environment where tests generate no revenues. The pharmacy, and the evolution of the pharmacist, may provide a model for successful adaptation to similar threats. Once upon a time, pharmacists manufactured pills, ointments and elixirs. Their value added was embodied in the process of production. Prepackaging, automated quality control and other innovations drastically reduced the value of custom individual on-site production. The role of the pharmacist has become that of information manager and clinical coordinator. Rather than defending the pill, they have become instruments for more effective control of pharmaceutical costs. Laboratorians must make a similar leap if they are to have a sizable role in the medical system of the 21st century. Attempting to hold on to traditional roles will mean that those functions are defaulted to physicians, nurses, administrators and other professionals in the health care system.

How to Conduct the Research

The end of cost-shifting means that most research, which has been heavily subsidized by patient care revenues, must obtain dedicated funding. It will may no longer be possible to enroll patients in clinical trials without paying for them. Unfortunately, the only ones likely to step forward with money for research are those firms that stand to benefit from the results. The need to demonstrate the value of laboratory services will be a tremendous boon to outcome studies, but the companies supporting those studies inevitably look on them as a part of their marketing effort. There will be a need to develop collaborative models for research which protect the objectivity of the process. Capitation will force laboratories to develop population based measures. The information system demands will be such that each test result, even from a hand-held analyzer, must be placed in a universal standard format, with a unique patient identifier up front. As systems become more integrated, the "hospital" and "clinic" will disappear as meaningful entities, so that the only appropriate denominator will be the individual (or collectively, a specified population).

What to measure

It will be necessary to understand the changes in the industry and how it is being transformed. It will often not be possible or worthwhile to investigate quantitatively the performance of each laboratory. Rather, research must focus on developing **structural indicators**, simple check-off questions that can be answered about organizational characteristics of the lab that are related to efficiency and quality (e.g., is the lab able to report rates of infection for defined populations? has the lab participated in developing of 2 or more clinical pathways or cost-benefit studies in the past year? to whom does the director of the laboratory report? and how well is their daily communication (not reporting) between laboratorians and clinicians, with evidence of changes in clinical practice, etc.?)

Medical Practice Changes

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Abstract: This presentation will deal with the fundamental changes which are resulting from the creation of integrated laboratory networks under the impact of managed care compensation influences, the acquisition of solo practices by hospitals and the shift of inpatient to outpatient services. The limitations on reimbursement are increasingly influencing the order patterns of physicians as a result of awareness that laboratory costs may have an indirect effect upon the take-home pay of the physicians. The changes in requirements for turnaround time will be analyzed in terms of the effect this is having on the shift from testing in core laboratories to near patient and point-of-care testing situations. The economic pressures are also beginning to force hospital and integrated laboratories to contemplate increasing automation and robotization as a way of streamlining testing and reducing cost of testing in general.

As these interactions occur, the pressure being applied to clinicians is to contemplate reduction or optimization of test ordering, including the development of ordering algorithms which, in turn, will tend to affect the menus of laboratories. The automation and robotics, coupled to intelligent electronic decision making processes, will tend to increasingly involve reflex testing decisions, which are going to influence both the logic of test ordering, as well as the total operation of laboratory systems.

Summary of Workshop 6: Measuring the Impact of Change on Laboratory Testing

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Key Questions

1. What data and information are needed to be able to measure the impact of change on laboratory medicine?
2. What methodologies could be applied?
3. What are some high priority research questions?

Conditions and Resources Necessary to be Able to Measure the Impact of Change

To conduct reliable studies, time series data bases must be established and maintained so that data will be comparable over time.

An inventory of data bases should be conducted including both private (e.g., ASCP Board of Registry, industrial, academic) and public (e.g. CLIA, state regulatory agencies, public health laboratories) sector data bases, especially those that contain time series data. An information clearinghouse should be established to allow investigators to locate these data bases.

Quantitative and qualitative data about laboratory practice should be collected over time, including: the number and type of personnel, distribution and tasks performed; locations of sites of testing, including types of laboratories, near patient testing, office testing, home testing, and testing in other kinds of sites. These data should also include an inventory of tests performed and their volumes; turn-around-time data; and information about tests referred from one laboratory to another.

Data dictionaries are necessary to standardize the terms and details of data collection so that data collected by different organizations or at different times are comparable. An example stressing the need for this is our inability to compare workload data because of the lack of a standard for defining the unit, "test."

A consortium consisting of government, industry, academic, professional organizations, providers and the public is needed to develop a research agenda that speaks to issues that are of importance and will provide answers of value to the funding entities represented in the consortium.

Research methods

Valid research data collection is dependent on developing a standard data dictionary that clearly and precisely describes the terms used in collecting data.

For the benefit of researchers, a

clearinghouse having an inventory of time series data, should be established. It is necessary to conduct an inventory of such data sources.

Using laboratory test results, it is possible to measure population health outcomes. Longitudinal surveillance of populations is a valuable public health tool.

Data relating to testing workloads should use relative values indexed to test complexity to standardize the scope of services performed in diverse kinds of laboratories. One such complexity relative value scheme is the CDC Complexity Model.

High priority research questions

1. Does the site of testing affect outcome? Consider both patient outcome and process issues such as cost, convenience and organizational efficiency.
2. How do changes in the laboratory aspects of the health care delivery system affect: cost, staffing, productivity, availability of tests and results, and individual patient and population health outcomes?
3. How effective has laboratory regulation been? Consider patient health outcomes as well as process issues.
4. Have clinical practice guidelines affected testing volumes, costs or patient outcomes?