The Impact of Managed Care and Health Care Reform on the Future of Laboratory Practice Research

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Abstract: To envision the future, it is necessary to look past the antithetical nature of managed care and health care reform, and to anticipate their rational convergence. Managed care is a regionalized, free-wheeling, health services brokerage business in which profits are optimized by selling high to high-volume purchasers, and buying low from a diminishing number of providers. Health care reform, a political process, is dormant, but was intended to nationalize health planning while improving accessibility and streamlining paperwork. Historically, excesses of capitalism have been tempered by governmental reaction. As yet, this has not happened in health care. Independent of the resolution of these politico-economic issues are the forces that are transforming societies throughout the world. Biotechnology and genetics, computerized communications, and globalization of commerce provide unprecedented opportunities for laboratory focused health systems research.

Fundamental health system changes are foreseeable. First, health systems will be large, vertically integrated businesses planned around the epidemiology, prevention and treatment of disease for community members. Financing will be integrated with health services delivery; providers will share in the economic risk. Health system relationships will be contractually acquired and maintained by outcome performance. The need to minimize unit costs and member utilization will be reconciled with the desire for universal accessibility.

Although predictable, renaissance in laboratory practices research faces significant challenges. New models and standards of laboratory practices will have to be developed in the context of lifelong, community member focused, health practices to include *pre-clinical, clinical and post-clinical* categories of laboratory services. Laboratory integration will require capital intensive, wide area computer networks connecting diverse points of service from home, physician offices and clinics, to hospitals and other computer systems. Laboratory services not only will be distributed throughout these networks, but research data will be gathered about member demographics, eligibility, accessibility, utilization, cost and *utility* (outcomes) of laboratory practices. Financing of laboratory practices research will be accounted as a cost of either marketing or quality assurance in the health businesses of the future.

Historically, the term “managed care” referred to a health maintenance organization (HMO), an organization of facilities and health care providers that offered a comprehensive range of health services to a group of enrolled members for a predefined premium which was paid in advance for a specified time.[1] These early organizations, dating back to the 1940s -- Kaiser Permanente in California being among the first -- were furthered by the Health Maintenance Organization Act of 1973

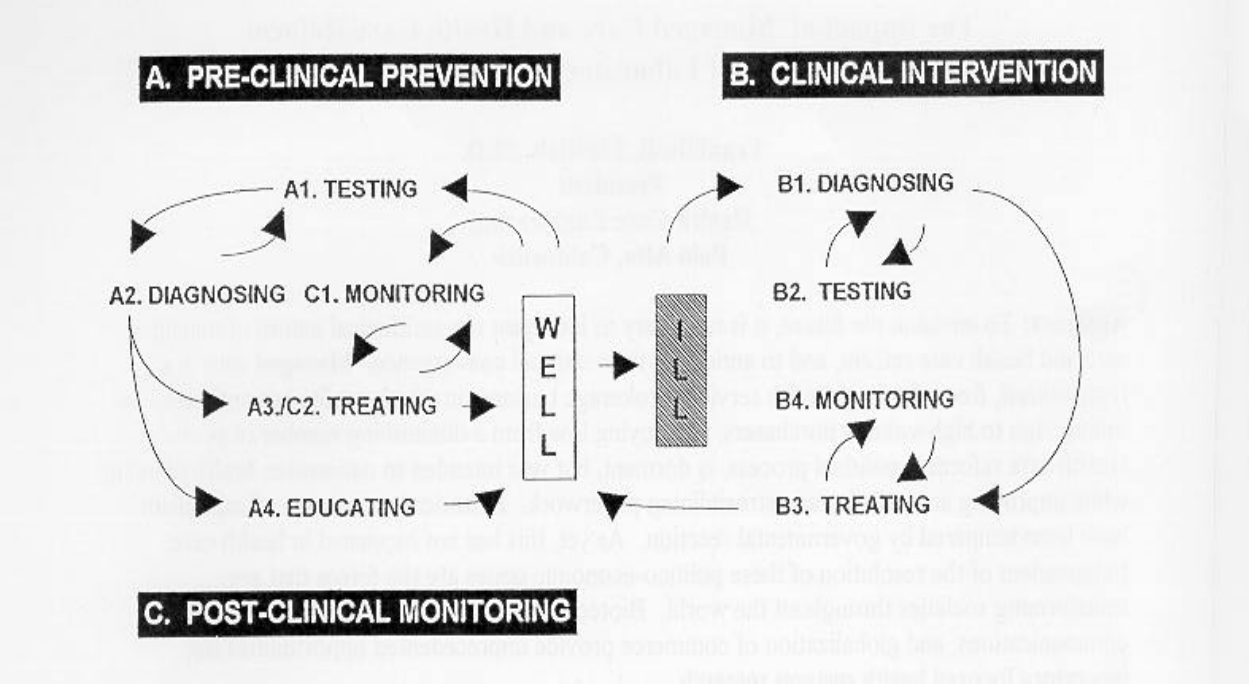

Figure 1. The clinical roles of testing and monitoring in controlling the processes of diagnosing and treating illness.

through grants and loans, in return for compliance with federal regulatory requirements for comprehensiveness and accessibility of services. In recent years, managed care has meant a variety of insurance plans in which the health care providers shared in the economic risk through either reduced fees for service or capitation.[2] When the Clinton health care reform initiative stalled in 1993, managed care insurance companies had gathered sufficient momentum regionally, particularly in California and Minnesota, that the movement quickly swept across the country. The opportunity for health care reform [3,4] and so-called managed competition quickly gave way to unbridled price competition among health care insurers, with only lip service paid to quality and accessibility.

During the past 2 years, the managed care movement actuated an unprecedented number of consolidations and mergers of hospitals and laboratories in their attempt to maintain economic viability. Employers, who for years had felt the brunt of cost shifting from reduced Medicare and Medicaid reimbursement, were eager responders to the allure of quality health care at predictably lower costs. Payers assumed that clinical laboratory quality was assured through federal and state licensure laws. The result has been a virtual revolution in the ethics, structure, delivery and funding of clinical laboratory services.

For laboratory practice research, the challenge from managed care is to demonstrate the value of diagnostic testing and therapeutic monitoring in the clinical management of both well and ill members of the health plan (Figure 1). While research

will continue to address better ways of *producing* clinical laboratory data and information, managed care and health care reform have created a public expectation that clinical services will be scored according to their beneficial effects on measurable clinical outcomes. The paradigm shift for laboratory practice research will be to scientifically demonstrate that testing has a measurably beneficial effect on the quality of clinical care in its *process control* role.

To envision the future, we have to look past today's harried financial aspects of managed care, which are no different in kind from those that occurred in this country at the last turn of the century. Then, too, perceived surpluses of the country's resources, timber, oil and minerals, faced insatiable consumer demands. Until surplus capacity of health care resources is wrung out of the system, a brokerage system of insurance will place onerous pressure on health care providers. On the other hand, providers must share responsibility for vulnerability to these pressures. We have been complacent about the influence of Wall Street on local health care institutions and practices and about knowledge of corporate business practice.

The political/economic issues swirling about health care should be regarded as effects, not causes, of the transformation of our health care system. The real drivers of change are familiar: biotechnology and genetics, digitized communications, and globalization of commerce. It is in these domains that laboratory practice research will find the technical and economic solutions to improved clinical outcomes.

We see that pre-clinical prevention is initiated with *testing* of well individuals (Figure 1). Post-clinical monitoring begins with measuring therapeutic blood levels of treated patients.. The opportunities for laboratory practice are unlimited in pre- and post-clinical health care, particularly as health care extends into the community and home. While multiphasic screening was disappointing, screening for specific illnesses has been rewarding, e.g., cardiovascular disease with serum cholesterol levels and cervical cancer with cytology. Future developments in pre-clinical testing will be based on genetics and molecular pathology. No greater ethical and technological challenges face us than implementation of testing for hereditary diseases. As clinical services extend into the community through point-of-care testing, the sites will be geographically distributed (Figure 2). Theoretically, a Community Health Information Network (CHIN) will link all of these sites with a secured, centralized data base accessible to care givers on a need-to-know basis. The research challenges of medical informatics, with its application to community-wide computer networks, are just being defined.

Computer networks will not only serve the clinical needs of communities but also provide the information necessary to measure clinical outcomes. Table 1 shows a matrix of clinical encounter quality indicators and examples of related measurable outcomes. As examples, seven quality indicators of clinical encounters are listed. In clinical intervention, the diagnosis is made by a clinician. The clinical laboratory provides test data that assist the clinician in treating the patient according to the diagnosis. If the member (not a "patient" yet) of the managed care plan is being evaluated for pre-clinical prevention, then testing precedes the diagnosis (cancer marker test precedes the diagnosis of genetic carrier). Treatment (as for hypercholesterolemia) or education (on

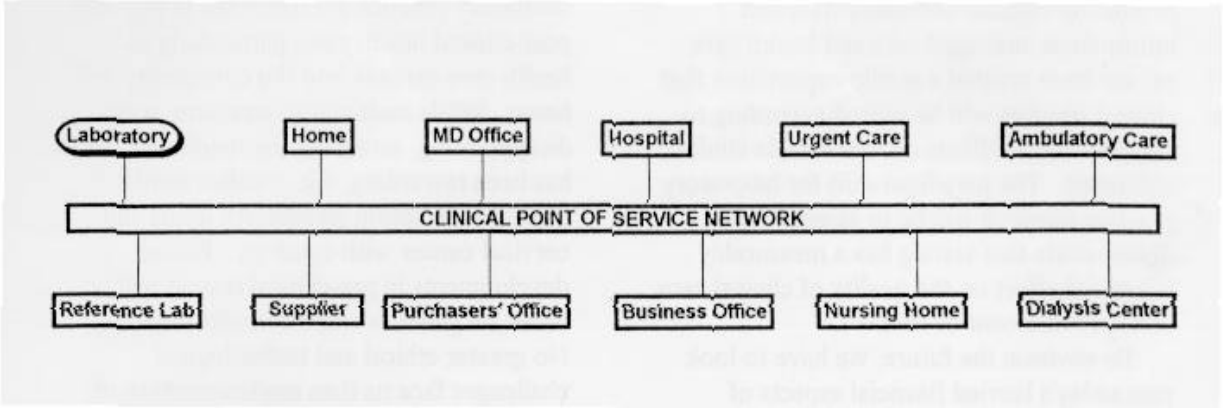

Figure 2. Geographic distribution of clinical services with administrative and logistical support sites.

OUTCOME MEASUREMENTS	QUALITY INDICATORS OF CLINICAL* ENCOUNTERS						
	Diagnosis	Frequency	Urgency	Duration	Redundancy	Satisfaction	Cost
	Predictive value of tests	Utilization of services	Acuity Co-Morbidity	Absenteeism Length of stay, visit or illness	Duplication of services	Patients' approval	Amount
TESTING PROCESSES THAT CONTROL CLINICAL* OUTCOMES Selecting, Combining, Timing, Obtaining, Shipping, Sequencing, Performing, Reporting							

*Including Pre-clinical, Clinical and Post-clinical encounters

Table 1. Outcome measurements of clinical quality indicators.

exercise, weight and diet for mild hyperglycemia) follow. If the plan member has been a patient (previously "ill") treated for myocardial infarction or stroke, monitoring of coumadin will follow. For the patient, diagnosis leads to treatment, with or without tests. In the outpatient setting, the clinician might test up to 20% of patients before treating, depending on history and physical examination.

In each of these examples, managed care plans ultimately will have requirements for measuring the outcome of clinical quality indicators. The National Committee for Quality Assurance (NCQA), founded in 1979 as an offshoot of the 1973 HMO Act, is leading the process through a set of performance measures designed to enable health care purchasers evaluate and track health plan performance through a benchmark system called HEDIS (Health Employee Data and Information Data Set). This year, NCQA is updating their current HEDIS outcome measurements. The outcome measurements listed in Table 1 are illustrative of future laboratory practice research projects.

In our hypothetical health plan, an outcome measurement score using Table 1 would be high for laboratory services if:

- High predictive value tests were used;
- Testing frequency was optimal for the clinical event;
- No testing deferral led to high-acuity illness or unexpected co-morbidity;
- No screening test was missed that led to absenteeism;
- Testing did not prolong clinic visits or hospital lengths of stay;
- No testing was duplicative;
- Patients were satisfied with laboratory personnel encounters (mostly phlebotomy);
- Cost was perceived to be fair and consistent.

Additional opportunities for laboratory practice research are listed in Table 1 as Testing Processes That Control Clinical Outcomes:

- Test selection
- Test combinations
- Timing of testing
- Obtaining specimens
- Shipping specimens
- Sequencing tests
- Performing testing
- Reporting test results

In the clinical context, not only will it matter that these steps have been performed properly but that they measurably increased wellness in the community.

The future success of laboratory practice research will require capital not only for new testing systems but for vast networks of computers for communications, and information management and analysis. Cost constraints ultimately may limit the speed at which rationalized health care can be achieved. The profound role economics will play in this process, however, means that laboratory practice research must incorporate economic and production expertise into future studies.

This is a time of unprecedented

opportunities for laboratory practice. Managed care has asked us, whether in academia or private practice, "What added value do you bring to health care?" The answer, in part, is that laboratory practice is a general, integrative discipline in health care, extending its body of knowledge from cradle to grave. Clinical testing is not a commodity, like soybeans, wheat or pork bellies, but an essential control process in all aspects of clinical care.

On the clinical level, if you ask clinicians what they want in their computerized medical record, the answer will be: Clinical problems, test results and therapeutic history. Even if only 6 out of the 30 patients seen in the office a day are tested--clinicians need the results with minimum patient delay in the office so that patients return to their homes without return calls to the office. This opens the avenue of research into design of future point-of-service testing networks.

Future health care systems are going to be bigger and more impersonal than those with which we are now familiar. Multimillion-dollar laboratories will remain, but multibillion-dollar hospital systems already are emerging. These new health care systems are going to be vertically integrated, meaning that laboratory practitioners will be corporate employees relating to medical and non-medical managers and peers. These systems will be community based, but could have regional or national ownership. Health planning will bring together epidemiology, prevention, and treatment from a community perspective. Research funding in the new health care organizations will be evaluated in the context of corporate marketing and quality assurance budgets.

In the future, business and health care will be integrated. The challenges of acculturation will be added to those of integrating financial and medical data bases. Current financial systems are outdated in the sense that they are not designed to handle both fee-for-service and capitated transactions. Medical data bases mostly are non-existent, or in irretrievable formats. Managed care depends on accurate information at every step, e.g., member eligibility, resource utilization, revenue, expense, outcome measurements. The research and development opportunities in integrated medical/financial data bases are unlimited.

Laboratorians will have to learn how to bid and manage capitated contracts. Commercial laboratories already understand the process. Unlike the past, however, when bidding could be low because of the expectation of "pull-through" fee-for-service testing, this is no longer an option. In the future, laboratories will be expected to bid like defense contractors who, presumably, know their actual costs of production. While most of us know our allocated costs, we are not likely to know our actual costs. To prepare a bid for capitated services, it is essential that we determine our actual costs. The companion issue, contracting, has replaced the warm, personal business relationship most of us grew up with. A handshake is no longer sufficient to acknowledge a business agreement. We have to learn to relate to attorneys who are specialized in health care business law. Laboratory practice research will have to incorporate knowledge of contract management and legal affairs.

Future health care systems, whether based on fee-for-service or capitation, will be required to minimize units costs. This means that allocated cost accounting will be replaced by activity-based cost tracking

systems. Future research will define the behavioral compliance and utilization patterns of health plan members as well as the productive behavior of health care providers.

In summary, the challenge facing laboratory practice research is to reach beyond the pre-analytical, analytical, and post-analytical thinking of the past to develop a new clinical perspective: The value of diagnostic testing and therapeutic monitoring is its beneficial effect on pre-clinical prevention, clinical intervention and post-clinical monitoring over the lifetimes of members of the community we serve.

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