Health Care Information Systems: Foundations for Future Research

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Abstract: Historically, health care information systems (HIS) have been designed to satisfy the needs and demands of administrators and clerks: laboratory managers, CFOs, the billing department. They have been purchased by providers as needs arose and linked together one at a time to satisfy specific requirements. These fragmented systems have been crippled by the distrust and parochialism that plague many health care organizations. The future of health care systems is brighter. Change is being brought about as a result of forces in both the health care and the information systems industries. Trends such as the move toward integrated provider networks, managed care, population based care and the computer-based patient record (CPR) are driving and facilitating the development of new HIS models. At the same time, dreams are becoming reality through rapid change in the information systems industry. In response, CIOs, laboratorians, vendors and consultants have sought to create a model for information systems that will preserve existing investments and functionality while at the same time addressing unmet needs and incorporating new capabilities.

The model that has been widely adopted within the HIS community is an architecture that unites disparate systems. It incorporates regional and national networks with local and wide area networks linking the component systems of the health care enterprise, such as the laboratory systems. These are bridged by an interface engine which channels data into a warehouse, or repository. This in turn provides a foundation for enterprise wide information systems as well as simple reporting and query functions. Advanced clinical systems built as enterprise information systems take advantage of emerging technologies to put information in the hands of caregivers at the point of care in ways that support and enhance the care process. This model incorporates all of the technologies identified in the Institute of Medicine's 1991 report on the computer-based patient record. It is, however, unable to resolve all of the shortcomings of information systems. For example, health care data pose significant difficulties. Definitions are not standardized, there are difficulties with coding and taxonomy, outcomes are still poorly defined, and much of the data is textual.

As this model becomes more widely implemented, it begins to make possible new capabilities within laboratory systems. To take advantage of these requires that lab systems development and research focus on issues of integration, intelligence, and imagination. Integration implies a longitudinal laboratory and health care record across time and space as well as the rejection of parochialism. Intelligence implies that our information systems think the way our caregivers think, display information effectively, and that they can understand and take action on the data they contain. Yet imagination may be the most critical focus of all, for it is what keeps us from doing things the way they have always been done when a new perspective would make all the difference in the world.

To properly consider laboratory focused health systems research, it is helpful to place laboratory systems within the context of the current overall health care information systems (HIS) environment. Historically, HIS have been designed and purchased to meet administrative and financial requirements, not those of caregivers. For this reason, they have developed as patchwork systems with a focus on acute care, each component being developed based on pressing business needs. Internal politics combined with weaknesses in system designs have led individual departments or providers to purchase and fiercely defend component systems that may not complement the overall HIS of an organization. Those individual components, each with its own technology, have had to be painstakingly linked together, one by one, into a complex web of interfaces. Caregivers seeking access to the information within these systems have often been daunted by user interfaces that require significant training and that, while useful to those for whom the systems are written, in no way reflect the work flow and thinking of a caregiver.

Change in the HIS industry has been catalyzed by factors in both the health care industry and in the information systems field. Emerging systems are redrawing the discouraging picture above. On the health care side, market-based health care reform such as managed care, and efforts at administrative simplification, are driving demands for comprehensive, standardized systems that effectively integrate administrative and clinical requirements. At the same time, provider consolidation into integrated delivery networks is forcing the creation of health records that span the continuum of care. Managed care strategists now look at health care requirements from the standpoint of populations rather than patients. This opens out the commercial health record into the realms of what have traditionally been the concern of public health planners and epidemiologists: data such as risk factors, immunization rates and the incidence of disease. Payers, including the U.S. Congress, are clamoring for cost savings through quality, efficiency, and "doing the night thing," a demand that has sparked the outcomes movement, the mass production of clinical guidelines, report cards, profiling and a host of other related initiatives all requiring information. Finally, health care information, once a private, written record for use by a caregiver and patient, has become a public utility to be collected by state and federal data commissions, disseminated over community health information networks (CHINs) and analyzed by researchers, planners, marketers and consumer interest groups. All of these trends demand true, comprehensive, integrated clinical information systems. The 1991 Institute of Medicine (IOM) report describing the requirements of the computer-based patient record (CPR) represents perhaps the clearest synthesis of these needs.

On the information systems side, the real catalyst of change is opportunity. This includes:

- Standard health care data definitions and interchange mechanisms
- Open systems, communications, security and data base standards
- Local and wide area networking
- Graphical user interfaces
- Text processing
- High powered, commodity hardware

All of these developments make it possible to

remove communication barriers between systems and providers, increase the distribution of information systems, and move data collection closer to the point of care, thus improving the quality of information.

Next Generation Systems

Given such complex new demands and the opportunities afforded by technological advances, providers have created quite a laundry list of requirements for the information systems they are looking to purchase and implement. Among them:

- Safeguard existing investments - Few providers are in a position to simply throw out their installed information systems base. Especially as integrated provider networks form, the disparate systems already in place must continue to do their jobs, at least for the short term.

- Preserve functionality - Likewise, the administrative needs already being met are not going away, though they are evolving. The addition of clinical functionality assumes the continued support of nonclinical functionality.

- Provide a foundation for expansion - Both of the information system and of the provider network.

- Support the continuum of care - Through required functionality, through a longitudinal patient record, and through access to information systems at the point of care.

- Incorporate a universal person index - Is John Jones also J. Jones also John J. Jones? A universal person index unites the records from disparate systems, both inside and outside the individual health care enterprise. Only with such an identifier can a longitudinal record be developed.

- Integrate - This requires moving beyond simple interfaces to create systems that truly span the health care enterprise. A classic example is health care scheduling where a patient may need a series of services in sequence. Interfaced systems make such scheduling a nightmare; integrated systems treat the challenge as a single whole.

- Supply new applications - New or redefined functionality demands new systems entirely. These may replace existing components, complement them, or use them as a foundation.

- Add intelligence - Human information process capabilities are finite. To extend productivity and reduce errors, the HIS needs to assume responsibility for routine processing and interpretation.

In response to this set of baseline requirements, HIS designers and developers are beginning to standardize on a generalized architectural model. While specifics of the model vary by implementation, the overall outline is as shown in Figure 1.

The boxes around the circle represent the components of the health care enterprise with their individual information systems. These are often referred to as legacy

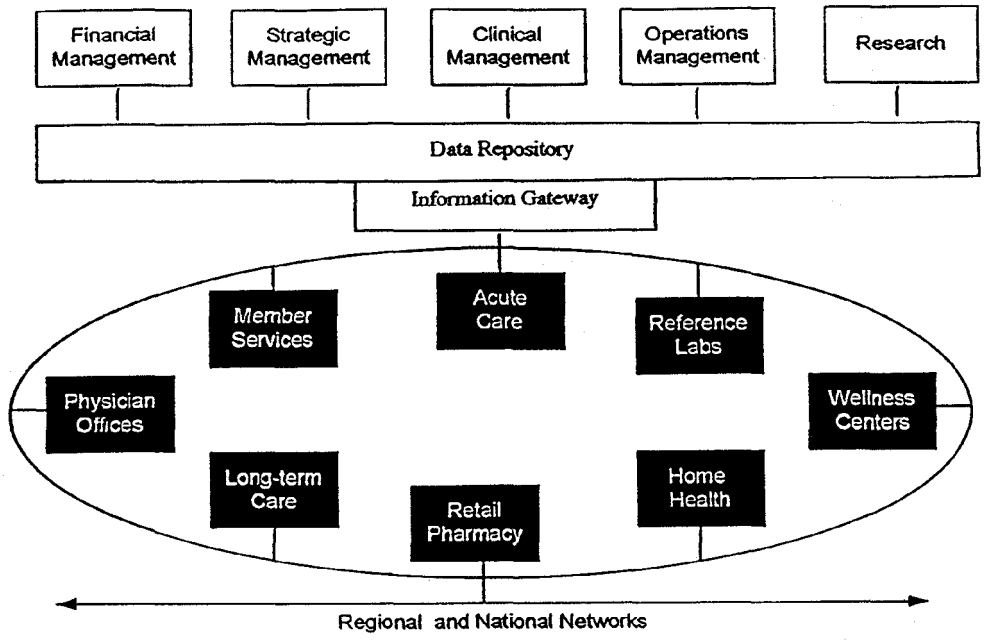

Figure 1. Generalized Architecture

systems, although in fact they may also be new systems that are specialized for a particular application. Each of these systems must meet operational needs and be able to collect component level data applicable to its functions. The circle itself is a local network around which these systems can pass information common to them, e.g., patient name and address or clinical condition. This local network is connected to regional and national networks (the "information superhighway") to which it can pass information and from which information can be obtained. For the care of an individual patient, the network might be used to gather the records of previous care by another provider. For outcomes management, it might be used to gather together a case sample of similar patients for analysis and comparison.

The information gateway might also be shown as part of the local network. It is a combination of traffic cop, facilitator, universal translator and general guide for all the bits and pieces of information flowing into and around the network. It knows which systems need what and can properly format and broadcast that information. It also knows what to extract for the repository. Finally, it includes a component to map everything together using a common person identifier. This makes possible the linking of disparate components of care into a single, logical, longitudinal record. The clinical repository provides a unified data base on which can be built enterprise-wide applications as the newly integrated health care organization determines its requirements. While it need not be a single, physical data base, it does need to be a rationally designed clinical record, providing caregivers with access to immediate,

accurate, and comprehensive information. It represents a data set that is both deep and wide. Deep in that it includes very detailed clinical data such as all of the tests and treatments received by a patient, their results, dosages, specific brand names, etc. Wide in that it includes not only a large sample of patients but care provided across the full provider spectrum. Across the top are shown broad categories of new applications. These can be developed and implemented efficiently when the clinical repository is in place. They, in turn, will enable its expansion by gathering and processing additional information.

To implement this model, developers will take advantage of the 9 technologies identified by the IOM in its model of the CPR.

- Databases and database management systems - For coping with huge volumes of disparate data.
- Workstations - Powerful multi-media hardware appropriate to the point of care/use.
- Data acquisition and retrieval - Implying user-friendly data entry and access at the point of care.
- Text processing - Simplified entry and meaningful retrieval techniques
- Image processing and storage - Both archiving of paper and clinical images
- Data exchange and vocabulary standards - To facilitate communications across components and organizations
- System communications and network infrastructure - To permit the widespread dissemination of systems to all caregivers in all locations.
- System reliability and security - To protect confidential data and ensure that systems are available whenever and wherever required.
- Linkages to secondary databases - To extend the model beyond a single health care enterprise, to incorporate knowledge bases, to provide benchmarks.[1]

Despite the advantages offered by the new model, there are a host of challenges yet ahead. For example, on the data front, the best information systems in the world cannot make up for missing or undefined data. At this point, outcomes data definitions are still loosely defined with little agreement across those doing the measuring. Even seemingly simple measures such as length of stay (LOS) may have different definitions within an organization, and more complex, yet familiar measures such as mortality have very different values depending on when and how measured.

Large components of health care data are not yet universally coded, or are coded using organization-specific schemes suitable for internal purposes but useless for public health purposes. Uncoded health care information is typically stored as text, which poses significant challenges of its own. While exciting work is underway in the area of automated text interpretation and coding, as of now, free text is not available for ready analysis or for operations such as decision support to caregivers. Other challenges have more to do with the structure of the health care system. For example, a true longitudinal medical record is predicated on a population focus for health care that spans proprietary organizations. Yet data are still "owned" by providers, insurers, and patients, and are in many cases a strategic asset. This is proving to be a serious impediment to many of the community health information

networks being formed.

Improving Care Through Laboratory Systems

Within the context of this model, laboratory systems have tremendous potential to improve the overall quality of health care. Without attempting a comprehensive catalog of projects, the three "I" words below summarize areas of focus likely to yield significant benefits to patients, providers and payers.

Integration. We have already discussed the mechanics of systems integration. Integration also implies cultural change and quality improvement to break down the distrust between departments and between clinical users and the information services department. One of the significant barriers to the integration of laboratory systems has been the traditional tension between "best of breed" systems and "house-wide" systems. Within the vendor community two trends are likely to reduce or eliminate this tension: One is the movement of lab systems vendors into the broader HIS market, and the other is the purchase and integration of respected lab systems by HIS vendors. The generalized architecture described above is also designed to minimize the integration "hit" from choosing a best of breed departmental solution.

An integrated systems model should also support the decentralization of functions where appropriate so that they are available at the point of care and/or where the caregiver works. If systems provide this level of integration, organizations are then free to reengineer processes, for example in a patient-focused care model, to improve the quality and efficiency of care. Finally, integration implies a truly comprehensive data model spanning time, location, provider and birth to death events. Only with such a model can we truly evaluate the outcomes of our processes, decisions and actions.

Intelligence. Intelligent systems are designed to think and work the way their intended users do. This means that information is presented in a flow and format that facilitates decision making and that parallels work flow. Intelligent systems also take on routine information processing so that users can focus on what is important and requires their clinical or managerial expertise. Laboratory systems have long flagged out-of-range values and provided basic interpretive information. More sophisticated systems provide for reflex testing, though this raises interesting legal issues. Newer systems will offer access to extensive knowledge bases, user control over the intelligence within the system and rules that examine data from the entire process of care to provide alerts and reminders to caregivers.

Imagination. Imagination implies thinking about how we can do things better, how we can reengineer a process to take advantage of computerization, and going beyond the routine solutions. A little creativity can go a long way in systems design and implementation. That includes looking not just at systems but at how they are used. Even the best system cannot overcome bad policies that defeat the system and jeopardize the quality of care.

After many years of promised advances remaining just out of reach, health care information systems are finally beginning to deliver their hoped for benefits to outcomes, quality and the productivity of caregivers. With proper focus, the combined expertise and attention of system designers and laboratorians applied to the issue of laboratory systems seems likely to yield a

rich harvest of rewards in the very near future.

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Deploying Information Technologies for Better Laboratory Use and Patient Outcomes: 20 Years at One Academic Medical Center

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Abstract: Skyrocketing costs and an aging population are driving U.S. health care toward bankruptcy: 15 % of the Gross Domestic Product is now being spent on health care. The key to solving this dilemma will be to cut fat from health care expenditures without sacrificing vital tissue. Despite the wide availability of computers and electronic media, the American health care industry still relies mainly on pen and paper to record and transmit information at many key points. Errors on paper records cannot be easily controlled and eliminated, while storage, maintenance, and access costs can consume more than 40% of a health care institution's budget and 25% of a health care provider's time. Mature and developing electronic information technologies can help improve care and lower costs by providing both generic information (knowledge), patient-specific data, and decision-support services.

At the Indiana University Medical Center, an electronic medical record has been created that contains most patient data (numeric and coded test results, drug use, diagnoses, clinical activity, textual reports, and itemized charges) for an urban tax-supported teaching hospital, a VA Medical Center, and their outpatient facilities. At the public hospital, this information system is serviced by a network of computer workstations for processing physicians' inpatient and outpatient orders while providing them with knowledge (e.g., an electronic version of Scientific American Medicine and the American Hospital Formulary Service Manual containing more than 1000 drug monographs), timely task and patient-specific data, and automated reminder rules and clinical practice guidelines.

Such interventions are themselves expensive, however, and despite flashy technology, should prove their worth in carefully performed studies before being broadly instituted. In a series of carefully controlled randomized trials, the authors have shown that computer reminders, feedback reports, automated guidelines, prior test results, display of test charges, and identifying high-risk patients can substantially alter diagnostic testing. Reminders, feedback reports, and guidelines doubled the ordering of appropriate preventive care screening tests and tests for monitoring of drug therapy and invasive procedures. Presenting prior test results and testing charges, and identifying high risk patients using data stored in patients' electronic medical records, lowered costs by 8 to 13% while maintaining (and even improving) the quality of care delivered. The inpatient microcomputer workstations that were the focus of much of this work incorporate many of the authors' prior successful interventions. When studied in a randomized, controlled trial, physicians using the workstations exclusively to write orders had hospital bills almost $900 (13%)

lower hospital bills. Length of hospital stays were shortened by almost a full day (11 %), and delays in initiating drug therapy were lowered by an order of magnitude while simultaneously reducing drug errors by one third.

As part of the National Information Infrastructure (the federal 'Information Superhighway" initiative), the authors have developed a high-speed network to support coordinated care and improved decision-making among 6 hospitals, more than a dozen satellite clinics and neighborhood health centers, and selected physicians' offices city-wide. Funded by the National Library of Medicine, this network will allow sharing of information between institutions during clinical encounters to reduce errors and avoid duplicative ordering of diagnostic tests and previous treatments.

High-quality health care is the sum of many small, often mundane decisions for which powerful information technologies will help cut costs and improve care while maintaining the physician's role as diagnostician and provider of empathetic interpersonal care. Reaching this goal will necessitate not only installing powerful computers and sophisticated programs throughout the health care environment, it will also require rethinking providers' roles to maximize the contribution of each health care team member's unique abilities.

Introduction

Health care costs are spiraling out of control. Health care now consumes more than 14% of the Gross Domestic Product, and this percentage is still increasing.[1,2] As medical costs rise, along with anticipated aging of the US population, American health care is approaching meltdown. In response, employers, payers, health care providers, and State and federal governments are searching for ways of reigning in health care costs without sacrificing the quality of care. Innovations to date have targeted both microprocesses (individual decisions) and macrosystems in health care and have included the following:

- **Managed care** where fee-for-service reimbursement creates incentives to increase the amount of health care delivered. Managed care is based on two premises: (1) payment for services is capitated, and (2) the care is managed by the practice to reduce waste and promote efficiency.
- **Restricted decision-making** where selected high cost and/or low yield health care tests and treatments, or those that have little effect on physician decisions or patient outcomes, cannot be ordered at all (e.g., restricted formularies) or require special prior approval.
- **Practice guidelines** where, to reduce variation in decision-making, care is guided by generally accepted algorithms that suggest actions but do not take the place of clinicians.
- **Care protocols** where decisions for selected conditions are dictated by care algorithms that largely remove clinicians from making most individual decisions.
- **Physician extenders**, such as nurse practitioners and physicians' assistants, who have varying amounts of decision-making authority and who often, to varying extent, follow explicit guidelines and/or care protocols.

Diagnostic tests are ripe for interventions to curtail their use because they have inflated

in price as fast or faster than other segments of health care and are often ordered or performed with little forethought or by inefficient general rules. Most diagnostic tests, especially those from the clinical laboratory, have little impact on decision-making and health care outcomes and are often unnecessary.[3-7] Reasons given by physicians for ordering tests with little informational content have ranged from "How do I know the patient doesn't have it [the outcome being sought]?" to "I might get sued."

A Model for Rational Test-Ordering

Physicians control more than 80% of all health care costs and order most diagnostic tests.[8] Therefore, this report will focus on ways in which physicians can become more parsimonious in their test-ordering. To enable physicians to get the most informational content out of clinical testing, Pauker has suggested a "threshold model" of clinical decision-making. Under this model, a rational clinician would order tests only if, in response to expected results, he/she would (1) neither treat nor test further (i.e., if the test is negative, the probability of disease would be so low that nothing further would need to be done), (2) treat the patient (i.e., if the test is positive, the probability would be so high that treatment should be initiated), or (3) order additional diagnostic tests (i.e., the test results in a probability estimate that is between the "no treatment/no further testing" threshold and the "treat/no further testing" threshold, as often happens with abnormal screening test results).[9] Most clinicians do not follow such a model when making decisions about testing and treatment, however, relying instead on heuristics (decision rules) that match clinical patterns of signs and symptoms with patterns of testing and treatment. Clinicians using such heuristics tend to err on the side of sensitivity (i.e., don't overlook diagnoses) and often do not fully exploit the incremental knowledge gained with each test result. By paying attention to the likelihood of disease, both before and after testing, and by having a plan of action (testing and/or treatment) contingent upon test results and patient characteristics, more informational "bang" can be obtained from the diagnostic testing "buck." Medical informatics offers tools to help achieve this end.

Medical Informatics and Quality Improvement

Information technology has been touted as an emerging tool to lower the costs of health care while improving its quality.[10] Managing medical information itself is costly: hospitals spend more than 40% of their operating costs on generating, storing, or retrieving information.[11] At the same time, physicians spend as much as 25% of their time recording or looking for information,[12] yet fail to find the needed information as much as 10% of the time.[13] The timely availability of electronic patient information could result in better testing by reducing the duplication of tests, making recent and prior results more available to multiple providers in multiple sites. Moreover, false-positive results, and the subsequent tests spent confirming or treating such results, could be reduced by targeting higher risk patients. Information technologies are expensive, however, and interventions to lower costs should themselves be cost-effective. Moreover, costs are only one outcome of interest: the impact of newer information processing systems (and the clinical systems within which they operate) on the quality of health

care should also be assessed. Therefore, information systems and electronic decision-support technologies should be studied, where possible, in controlled clinical trials before becoming widely disseminated.[14]

In the past several years, the methods of industrial quality improvement have become widely used in medicine.[15] As applied to diagnostic testing, the quality improvement model is information-intensive and requires measurements of health care processes in addition to objective and subjective (patient-centered) health care outcomes. Thus, studies of informatics interventions have used captured clinical data to both generate their interventions and assess their outcomes. Interventions to improve diagnostic testing that we have studied include continuing education, feedback of performance, generic and patient-specific reminders, and automating clinical practice guidelines. Each of these interventions have been shown to be most powerful if they were specific to the individual physician and were continuing: in our studies and those of others, when the interventions were discontinued, the physicians reverted back to their prior behavior patterns.[8] Medical informatics offers the ability to continue successful interventions indefinitely because most of their costs are front-end loaded so that, once the intervention is initiated and proven effective, there is little maintenance cost.

20 Years of Experience in Indiana

For more than two decades, we have used the data and processes of a comprehensive electronic medical record system to improve physician decision-making in an urban teaching hospital and its outpatient general internal medicine clinic.[16,17] For example, computer-generated reminders to perform outpatient preventive care improved compliance with accepted protocols from 29% to 49% (Figure 1).[18] Moreover, timing was critical: feedback reports of patients who had been eligible for preventive care but had not received it had less effect than reminders that were delivered to physicians at the time that they were caring for eligible outpatients (Figure 1).[19] Computer-generated reminders also outperformed an intensive continuing education intervention which had no significant effect on physician behavior.[20]

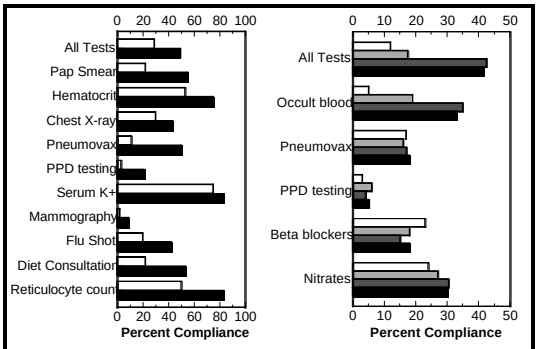

Figure 1: Controlled trials to improve compliance with preventive care. Left=Computer reminders vs. control (white bars). Right=Control (top bar) vs. feedback (2nd) vs. reminders (3rd) vs both (4th)

For increasing the timeliness of informational interventions to improve clinical decision-making, we created a network of physicians' microcomputer workstations for writing outpatient test orders.[21] Once they became the sole means for ordering outpatient diagnostic tests, the workstations could provide the physician, while he/she was writing orders for a patient, with information that was specific to that patient and the test being ordered. In a series of controlled trials (Figure 2), we found that outpatient test-ordering could be reduced, with no diminution of the quality of care, by displaying prior test results,[22] test

prices,[23] and calculated likelihoods that the tests would demonstrate the specific abnormality being sought.[24] In each case, when the intervention was terminated, test-ordering returned to pre-study levels.

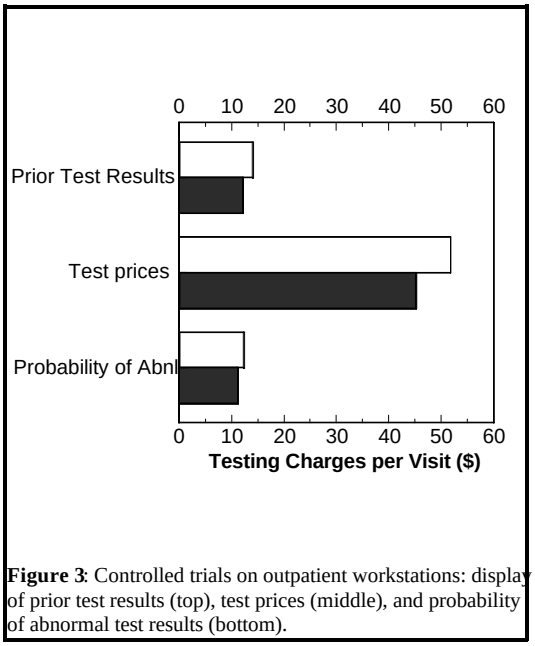

Figure 3: Controlled trials on outpatient workstations: display of prior test results (top), test prices (middle), and probability of abnormal test results (bottom).

Next, we moved to a more intensive venue: the hospital. We programmed our workstations so that physicians could write all inpatient orders using any of the workstations located throughout the hospital. The physician did not have to be on the patient's ward nor have the paper chart in hand to write workstation orders which were sent electronically to the appropriate hospital department (e.g., pharmacy). As in the outpatient studies, patient- and problem-specific information could be displayed to the physicians at the time that they were making clinical decisions. The information the workstations routinely displayed included prices, the existence of prior results, and, where indicated, "negative detailing" information meant to discourage the ordering of items deemed by our subspecialists to be costly and of marginal or no value. For many clinical problems, the menus that guided ordering contained the most common tests and treatments. In addition, the physicians could access an electronic textbook of medicine and the American Hospital Formulary Service manual with more than 1000 drug monographs.

In a 16 month randomized, controlled trial involving more than 5000 inpatients, physicians using the workstations generated hospital bills $887 less per admission than control physicians who used paper charts to write all orders.[25] Similar reductions were found separately for diagnostic tests, drugs, and facility charges. Intervention patients were discharged almost a full day earlier and had one-third fewer drug-related incidence reports. Moreover, no difference was found between intervention and control patients in post-discharge outpatient or emergency room visits, outpatient charges, or hospital readmissions. We concluded that using workstations to both write orders and receive patient- and order-specific information could result in lower charges without compromising, and arguably improving, the quality of care delivered.

Once proven to be useful and cost-saving, the workstations became the sole means for writing all orders on the inpatient and ambulatory general internal medicine services and thus provided a medium for subsequent interventions to lower costs and/or improve the quality of care. We next studied clinical practice guidelines where the workstation system would continually process information for all inpatients and create guideline-specific "suggested orders" that the physicians could select with a single keystroke (or ignore if they disagreed with them). In a six-month randomized,

controlled trial, half of the physicians received suggested orders generated by guidelines for monitoring of drug therapy.[26] For example, an order for an aminoglycoside antibiotic was followed by suggested orders for bi-weekly renal function tests and trough and peak aminoglycoside levels.

When provided with suggested orders, the intervention physicians complied with drug monitoring protocols 49% of the time compared with 29% for control physicians (Figure 3).

Simply displaying information and encouraging behavior however, is not sufficient to engender a response in physician behavior. Physicians must also agree with

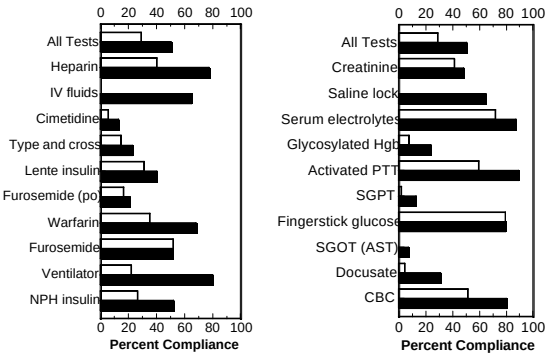

Figure 4: Results of controlled trial on inpatient workstations of automated guidelines for monitoring of drug therapy showing results by triggering orders (left) and suggested orders (right).

the protocol's content. For example, when we programmed the workstations to suggest orders for inpatient preventive care, using the same protocols to which the physicians responded to in the outpatient clinic,[18,19] no significant differences were found between intervention and control physicians.[27] In response to a survey, the physicians stated that they did not feel that the inpatient service was an appropriate venue for performing preventive care. Thus, in addition to being timely, the underlying algorithms must be acceptable to the physicians.

Lessons Learned

What have we learned from 20 years of work using electronic medical records to improve physician decision-making and diagnostic testing?

- Physicians respond to various informatics interventions that are delivered in a timely manner, represent acceptable clinical decisions, and are patient- and problem-specific.

- Physicians can be encouraged to both increase the ordering of under-used tests (e.g., for preventive care or monitoring of inpatient drug therapy) and reduce the ordering of over-used tests.

- Inserting electronic information management into the processes of care provides an opportunity to provide generic and problem-specific information at the very moment that physicians are making clinical decisions.

- Physicians will not only use computer workstations,[28] they will respond to interventions during on-line order-writing to lower costs and improve the quality of care.

Future developments should further broaden the reach of electronic record systems in order to move large amounts of

medical knowledge and patient information between geographically separated health care venues. As electronically stored data become more detailed and plentiful, better guidelines and systems for implementing them will be developed that will further reduce variation and waste in health care. Provider roles and time commitments will evolve away from spending enormous amounts of time on recording and extracting information and towards information synthesis and providing humanistic care. In such a way, one of the most technologically sophisticated aspects of medicine, electronic records, may not only improve the quality of care and control costs but also positively affect one of health care's least technological aspects: the doctor-patient relationship.

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Hospital Systems That Put Patients at Risk

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The number of patients who accidentally die or are injured in our nations hospitals is roughly equivalent to three jumbo jet crashes every other day . I'm sure most of you have heard these statistics before, yet each time I hear numbers like these I'm amazed that a country rich in HEALTH CARE like ours does not do better. There are, however, ways that can improve this statistic and at the same time reduce the costs of delivering good health care in the United States. The following three points suggest an approach to start to improve the standard of care in our nation's hospitals:

- Standardize Procedures
- Improve Computer Systems
- Improve Communication Between Patient Care Areas

Put very simply, we need to examine the structure, processes and outcomes of the clinical care provided to the patients in our hospitals. A recent article in the Journal of American Medical Association (JAMA) states that errors in drug therapies result in 200,000 injuries / year and that preventable medication errors occur in 2 of every I 00 hospital admissions. The statistics quoted for pharmacy are measurable, but how do we examine the errors that occur in our laboratories (Table 1)?

As we understand the possible causes of some of these errors, the ability to change the process becomes abundantly clear (Table 2).

Once again, the focus should be on the systems, processes and outcomes.

Changes in Health Care and the Effects on Quality Care

As the reimbursement dollar shrinks, we begin to experience rapid transformation in the health care industry. Thus exists the opportunity to transform the systems currently in place to improve the quality of care. Some of the more prominent changes and their anticipated effects are listed in Table 3. We should examine each of these change/effect scenarios independently.

In an effort to reduce costs in the health care industry many corporations and individual hospitals are forming alliances or ***merging.*** The larger the entity the more opportunity to reduce costs through volume purchasing and sole source contracts with companies that are at the same time buying new businesses. The trend in both hospitals and manufacturers is "larger is better." Lower prices for health care products are necessary, but the real cost savings will only come through the proper utilization programs. Standardizing on a single product will present the opportunity for the staff to familiarize themselves with that product and will require less training on use.

Secondly, the inevitable shift to ***managed care*** will place the emphasis initially on

PROBLEM	RESULT
Test Order or Transcribing Errors	Clinical Treatment Delayed
Blood Drawing Errors	Clinical Treatment Not Appropriate
Improper Quality or Quantity of Specimen	Clinical Treatment Delayed
Malfunction of Instrument	Clinical Treatment Delayed
QC or Instrument Calibration Error	Clinical Treatment Delayed
Test Reporting Error	Clinical Treatment Not Appropriate

Table 1. Potential result of errors that occur in the laboratory.

ERROR	POSSIBLE CAUSE
Blood Drawing Errors	Improper Training of Personnel
Improper Quality/Quantity of Specimen	Improper Training of Personnel
Malfunction of Instrument	Improper Maintenance of Equipment
QC or Instrument Calibration Error	Inadequate Equipment
Test Reporting Error	Poor Computer Systems

Table 2. Possible cause of laboratory errors.

CHANGES	EFFECTS
Hospital Mergers	Create Opportunity to Lower Costs
Shift to Managed Care	Effects Remain to be Seen
Consolidation of Services	Increase Quality of Outcomes
Downsizing of Staff	Do More with Less
Increase Emphasis on Automation/IS	Increase Quality of Outcomes

Table 3. Effect of changes in health care industry.

reducing operating costs and eventually to more emphasis on "Outcomes Measures." With the focus on outcome measures, the logical change in processes and improvement in information systems will result in increased quality of patient care. To be competitive in the managed care market, the providers must be able to produce clinical data on their patients and relate those data to the clinical outcomes. The focus here is on "outcome measures." Although many people agree that it will be the goal of the future in health care, very few experts have developed the process to monitor and document meaningful outcomes.

As most of us realize, the leading consultants in health care today are all advocates of ***consolidation.*** As we also understand, this project is much easier talked about than implemented. As the alliances and merged hospital networks work toward consolidation, the result is a higher volumes of testing, an example of a system change that will ultimately result in increased quality of care. The more tests performed by the staff, the more competent the staff will be. As the test volumes reaches a critical mass, the next logical step in the process is robotics and automation. This is the place where we begin to see the real savings and increase in the quality of the testing.

Even before the consolidation of services process moves into the automation process, the ***downsizing*** of the ***staff*** is inevitable. The opportunity for the medical technologist to become involved with yet another system change to improve quality exists. Medical Technologists will have the opportunity to work on test utilization programs with the physician, patient focused care teams, and information system teams that improve the communication between patient care areas and physicians and hospitals.

The primary goal that we should be working toward, as we strive to improve health care systems, is to deliver the *right result to the right person at the right time.* Information is the product that the laboratorian of the future produces. Automation and robotics will be the tools we need to achieve that goal. The positive effects that automation will have on laboratories of the future are:

- Improved turn around times
- Lower the overall error rate
- Ability to increase volume without increasing staff
- Less specimen required
- More emphasis on information, less on systems

COLUMBIA/HCA
COMPANY PROFILE

HOSPITALS	326
BEDS	81,000
EMPLOYEES	212,000
ANNUALIZED REVENUES (billions)	$17
OUT PATIENT SURGERY CENTERS	127
PHYSICIAN OFFICE PRACTICES	800

All of the changes required of a successful health care system in the future remain to be seen. The emphasis must be on changing the systems as they currently exist. As we see the industry in transformation the goals of the most successful organizations are: increasing efficiency and productivity, integrating all major services, maintaining and improving quality of care, and reducing costs to be price competitive. Most important is to be able to respond to and embrace change. Columbia Health care is the largest existing corporation worldwide, and because of this size we have been very successful in reducing the costs for the entire

system. Reducing costs, however is only the first step. The significant savings potential will be realized when the utilization programs and the consolidation efforts are successful. The four strategic goals of the Columbia Material Management Strategy are:

- Reduce costs through volume contracts
- Standardize products to reduce waste
- Partner with physicians and suppliers
- Measure and improve utilization of products

The way to improve quality is to set standards and measure and improve from a benchmark. The difficulty with the laboratory setting standards is the wide variations of instruments, test methodologies, and the utilization in the reagents, etc., required to produce the test results. As Columbia reaches the goal of standardizing the products, the company will be in a position to benchmark these procedures. Imagine a network of hospital laboratories in a region with identical laboratory instrumentation, identical lots of reagents and quality control material, identical training programs for the technical staff, identical reference ranges for the entire market (same population), identical information systems with the electronic medical record where patient data will be available to the physician in all settings in the market. The following (Figure 1) represents a simplified structure charting the consolidation strategy for Columbia laboratories.

The Columbia strategy for consolidating the laboratories in a network stress the following key steps:

- Sharing of esoteric tests
- Linking the information systems
- Common bidding process for residual reference lab tests
- Common equipment and supplies
- Developing "Centers of Excellence," sharing professional expertise in the company
- Common outreach services in a market, to include marketing, sales, billing and client services

In a recent article in JAMA entitled *Systems Analysis of Adverse Drug Effects*, the author lists 16 major systems failures. The following is a similar list that can be compared to systems that need radical improvement in the hospital laboratory:

CAUSES OF LAB ERRORS SIMILAR TO CAUSES OF ERRORS IN THE PHARMACY

1) Lab Test Knowledge	Physicians unaware of a specific lab test and when to order
2) Patient Information Availability	Patient history was not available to the clinician when needed
3) Order Transcription	Manually transcribed orders leads to misinterpretation
4) Interservice Communication	Poor communication between departments in the hospital
5) Device Use	Improper specimen container for collection
6) Collection Times for Drug Levels	Dosing times are not a standard protocol in all hospitals
7)Standardization of Procedures in	Different procedures exist from one unit to another hospitals
8)Transfers/Transition Problems	Identification errors when patients are transferred
9)Conflict Resolution	Many of the staff unaware of policies or procedures
10) Staffing /Work Assignments	Inability to match staffing to the current clinical load
11) Feedback on Error Resolution	Staff was not educated to the follow up on errors

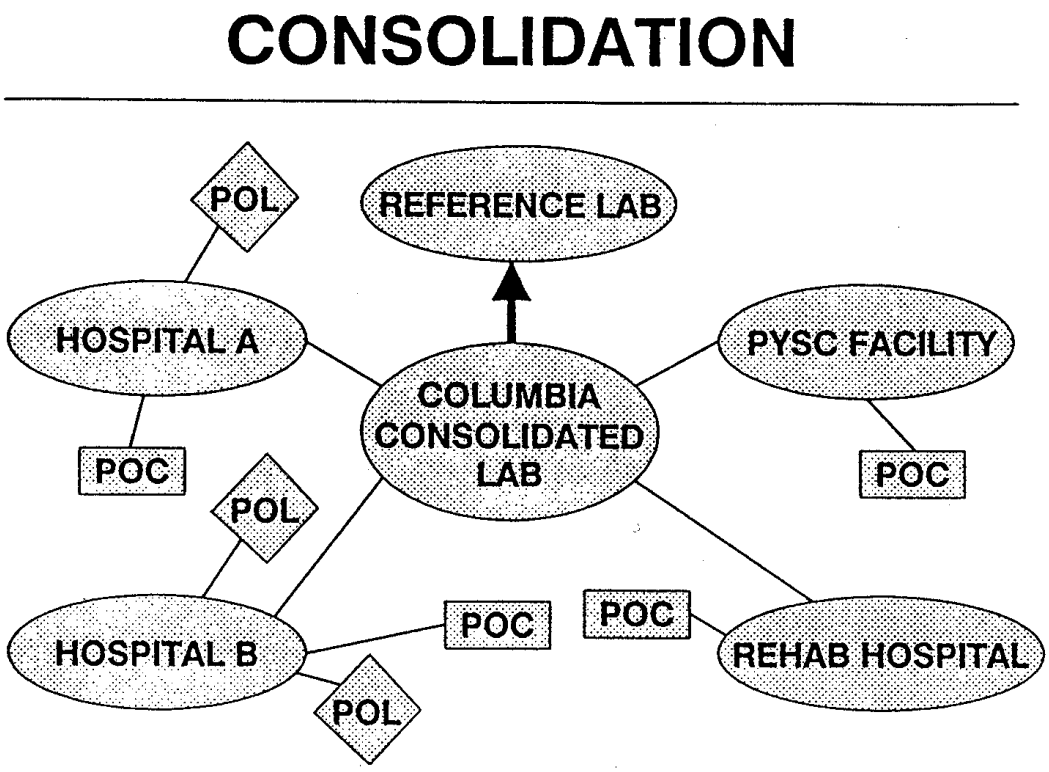

Figure 1. Consolidation strategy for Columbia laboratories.

This exercise proves that of the 16 system problems documented in the JAMA article, 11 of them can be directly related to the laboratory as well as the pharmacy. If such major system problems exist that are similar in most of the ancillary departments, why do we not form interdepartmental committees to identify and resolve the problems common to these departments. In a separate article in JAMA the author suggests that ADE's increase patient care costs by $2000 per day. Therein lies the opportunity to decrease costs by improving the quality in our hospitals.

In summary, the restructuring of the reimbursement system in the health care industry is inevitable. What is not so obvious are the opportunities that present themselves to better the delivery systems. In short, we should forget the old way of doing business, examine the processes, locate the causes of inherent errors, maximize the use of computer systems and proceed to measure the improvement. Once we have the ability to standardize the processes and computerize the approach, we will have good access to data. When the health care networks are functioning as one, instead of individual business units competing for the reimbursement dollar in their market, we will have the ability to follow a patient through the continuum of care and to compare the outcomes of the various treatments in each clinical setting.

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Role of the Laboratory Professional - New Opportunities

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Abstract: New service opportunities for professionals in laboratory medicine parallel the new research opportunities in laboratory medicine health services research. Clinical laboratorians must extend both their clinical and research agendas beyond the confines of the clinical laboratory, forming multidisciplinary teams to address the key issues that add value to the health care delivery system. A new focus for laboratorians on cost-effectiveness and outcomes assessment is a vital component of the new research agenda. For example, test evaluations performed properly and comprehensively are a form of outcomes or effectiveness research. A rapidly growing Laboratory Medicine Health Services Research Program at the University of Alabama at Birmingham is an example of a program focused on these important issues. Using a truly multidisciplinary approach focused on hypothesis-driven research, this program has achieved extramural funding from multiple sources. This success emphasizes the excellent new opportunities available for investigators in laboratory medicine health services research.

The instability of the current health care system and the ongoing revolution in health care delivery has created new opportunities for laboratory medicine physicians and scientists. Many of these opportunities exist in the service environment. However, new opportunities in service activities translate directly into new investigative opportunities. Many of these are focused on the assessment of cost-effectiveness and outcomes, which underlie essentially all strategic decisions in the new health care environment. The professionals in laboratory medicine are in an ideal position to take advantage of this paradigm shift. Three key components of the health care delivery system are patients, providers and payers. Traditionally the laboratory medicine profession has rendered services primarily to health care providers (physicians who order tests) and have generally avoided the other elements, the patients and providers. The successful implementation of new service programs in laboratory medicine must focus on adding value to all three axes, not just the providers.

New service opportunities for clinical laboratory consultants (physicians and scientists) overlap with new research opportunities. Seven of these are listed in Table 1. Discussion of each of these is presented more extensively in the original article by McDonald and Smith.[1] However, it is important to stress that laboratory medicine consultants must add value to the health care system and the value added must be proven by health services research.

Service: Valued Added and Medical Relevance

1. Management of point of care testing: at any location
2. Information systems: laboratory and health care system wide
3. Consultants - clinical care
4. Resource managers: for laboratories and broadly in health care systems
5. Utilization management
6. Quality assurance
7. Technology assessment and implementation

Table 1. Expanded Service Opportunities for Laboratory Medicine Consultants [1].
([1]Adapted from Reference 1)

- Effectiveness
- Efficiency
- Appropriateness
- Technical Assessment of New Analyses

Table 2. Components of Laboratory Medicine Health Services Research.

Laboratory medicine consultants are equipped to be consultants in the management of point of care testing, no matter where and by whom it is done. Laboratory medicine consultants are experts in information systems as they apply to laboratories. The challenge now is to extend this expertise beyond the laboratory to the entire health care delivery system. Of course professionals in laboratory medicine are clinical consultants) but health services research has not been performed to prove their value, especially in the all-important primary care setting. Although laboratory professionals manage resources in the laboratory, they must be prepared to do so as consultants beyond the laboratory. Utilization management can be expressed in many ways in health care, including preparation, implementation and management of health care guidelines. The roles for laboratory medicine specialists in quality assurance and technology assessment and implementation are well defined in the laboratory. The new challenge is to use this expertise in areas outside the laboratory.

The laboratory is clearly an important focus for cost-effectiveness research. Approximately $100 billion is spent annually on laboratory testing with little, if any, prior cost-benefit analysis.[2] Utilization is non-standardized, however, and geographic variation in utilization has been well documented.[3] Since expenses are encapsulated, they are relatively easy to measure, at least in the aggregate. Finally,

laboratory testing is in a unique position in the health care system affecting essentially all levels of the health care system, from the home to the hospital.

Laboratory medicine health services research is a general term that encompasses clinical investigation focused on the impact of laboratory medicine practice on the quality and cost effectiveness of patient care. It includes, at a minimum, the components shown in Table 2. Effectiveness research as used here is synonymous with the more commonly used term, outcomes research. Effectiveness research focuses on developing and refining methods to identify high quality, cost-effective health care.[4] It includes evaluation of technologies and practice methodologies. Efficiency is the quality of output divided by the consumption of resources (cost) and is clearly a vital component of laboratory medicine research. Appropriateness defines the best use of medical technology in practice and must be highly focused on specific problems to be successful. These are all important components of the assessment of new technology, and are clearly the purview of laboratory medicine professionals. But like the service opportunities listed in Table 1, these research activities must be broadly defined to include traditionally extra-laboratory issues and must be actively and creatively pursued by laboratory professionals.

Test evaluations, properly performed, are one form of laboratory medicine health services research. Some general, rather obvious, principles that must be evaluated in any comprehensive test evaluation include patient outcomes and cost-effectiveness. A comprehensive cost analysis is vital and must include a breakdown into direct, variable, and fixed costs, since not all costs will be equally affected by the inclusion or omission of a procedure. Effectiveness or outcomes analysis involves assessment of many potential endpoints, a fact often overlooked by new investigators in the field. Some of these include such things as patient satisfaction, patient time in office, frequency of follow-up visits, and time away from work. Test evaluations must also develop criteria for appropriate utilization and consider whether newer methods should replace older methods or be added to the testing menu.

The keys to success in performing laboratory medicine health services research include these three principles: (1) the laboratorian must get out of the laboratory and into other administrative and clinical arenas of the health care system; (2) the laboratorian must lead or participate in multidisciplinary teams) all outcomes investigations are, by definition, multidisciplinary; and (3) all investigations must be hypothesis-driven. Omission of the last item is the most frequent and fatal error. If an hypothesis is not tested, the activity is not research, and conclusions cannot be extrapolated into future endeavors. Many additional key variables must be assessed when performing laboratory medicine health services research. As shown in Table 3, the impact of the provider, the service provided, analysis location, and the patient environment or location are all potential variables that may affect an outcome) and can, and should, influence the design of the research protocol. A separate area of research in laboratory medicine worth emphasizing is information management.[5,6] Information systems expertise is needed throughout the health care system in both service and research. For example, extraordinary opportunities exist in

Provider:	Self, paramedical practitioner, primary care physician, specialist physician
Service:	Laboratory analyses, quality assurance, utilization management, information system changes, analysis of aggregate or individual patient data
Location:	Home, hospice, nursing home, pharmacy, office, clinic, hospital

Table 3. Important Variables that Affect Outcomes in Laboratory Medicine Health Services Research

identifying appropriate uses for aggregated patient care data in assessing the quality and cost-effectiveness of health care.

Many groups, public and private, fund laboratory medicine health services research. The breadth of funding opportunities is, in many ways, more expansive than for basic research. Most importantly, the funding opportunities are increasing) not decreasing. Some of the agencies or groups that fund laboratory medicine health services research are shown in Table IV. The Agency for Health care Policy and Research is a government agency focused on cost-effective health care delivery. It funds the development of health care guidelines and protocols and funds individual and patient outcomes research team (PORT) grants. The Centers for Disease Control and Prevention (CDC) funds various kinds of contracts, especially those focused on the impact of laboratory quality. The National Library of Medicine funds programs focused on information systems in health care delivery; Dr. Donald Lindberg, Director of the National Library of Medicine, is both a pathologist and a pioneer in this field. The Veterans Affairs research program has some targeted programs, as do selective branches of the NIH (e.g., the National Institute of Nursing). Some private foundations, such as those listed in Table 4, have special interest in outcomes research and cost-effective health care delivery.

Industry must not be forgotten. Various product lines within the industrial sector are involved in cost-effective health care delivery. The funding of extramural research programs by managed care providers is vital, but it is new behavior for them. Hospitals also have renewed interest, given their conversion from revenue centers to cost-centers. Other Federal agencies such as the National Institute of Standard and Technology (NIST) has a health care information systems program through which the University of Alabama at Birmingham (UAB) Laboratory Medicine Health Services Research Program is being partially funded. Unfortunately, NIST is a branch of the Department of Commerce which is currently under extreme political pressure. Thus, the fate of this program is unknown. Finally, there are other Advanced Technology Programs funded by the government which can link industry to academia and which may be sources of funding, especially if new technology is being assessed.

The multidisciplinary Laboratory Medicine Health Services Research Program at UAB has multiple components as shown in Figure 1. The core programs include

1. Agency for Health care Policy and Research
2. Centers for Disease Control and Prevention
3. National Library of Medicine
4. Department of Veterans Affairs (VA)
5. NIH - e.g., National Institute of Nursing
6. Private Foundations - The Whitaker; Robert Wood Johnson
7. Industry - Varied product lines (insurance, reagents, equipment, HMOs and other provider groups
8. Hospitals
9. National Institute of Standards and Technologist (NIST)
10. Other Federal Advanced Technology Programs (ATP)

Table 4. Funding Opportunities for Laboratory Medicine Health Services Research.

outcomes or effectiveness research, clinical research support, product evaluation, education and informatics. This program supports developmental research in laboratory medicine and interfaces with numerous medical center outcomes-focused research programs. In addition, the program has laboratory-initiated projects in which laboratory medicine professionals are principal investigators. Examples of these projects include: (1) a subcontract with Cerner Corporation funded by NIST designed to automate laboratory practice guidelines on computers; (2) a project designed to develop a sentinel monitoring network of clinical laboratories focused on assessing quality of testing and the impact of CLIA '88 (funded by the CDC); and (3) another project recently funded by the CDC to develop an investigational consortium focused on the relationship between laboratory performance and patient outcomes. These independent research programs have all been funded within the last year and represent examples of the extraordinary opportunities available to support this kind of research.

In summary, new service opportunities in the emerging era of managed care and health care reform parallel new research opportunities in laboratory medicine health services research. Comprehensive test evaluations, which test an hypothesis and are properly performed, are forms of outcomes or effectiveness research. In addition, the interface between information systems and the health care delivery system represent unique opportunities for focused laboratory medicine-driven research programs. Finally, new funding opportunities are available for high quality laboratory medicine health services research.

In conclusion, this time of rapid change in the health care delivery system has created new and exciting service and research opportunities. Laboratory medicine

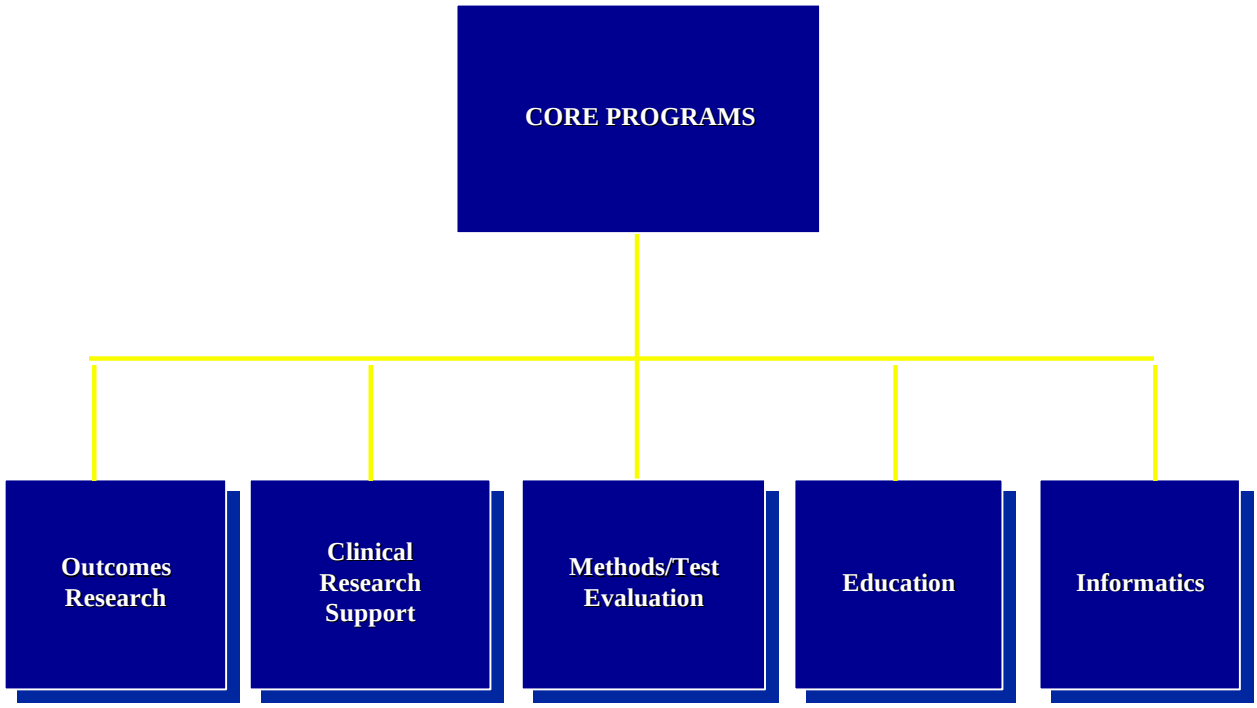

FIGURE 1

Figure 1. UAB Laboratory Medicine Health Services Research Program core activities.

professionals must take advantage of these opportunities, which will have broad impact on health care enterprise and allow laboratory medicine to be practiced at a new level with different boundaries than before.

Acknowledgments

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Summary of Workshop 7: Laboratory Focused Health Systems Research

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Key Questions:

1) What can be done within our present system of delivering laboratory services to improve patient outcomes?
2) What can be done in the future to design better systems to achieve higher quality laboratory services?"

The Workshop on Laboratory Focused Health Systems Research had the objectives of:

- facilitating a discussion of the delivery of quality laboratory services in primary, secondary and tertiary care settings;

- developing strategies that demonstrate the differences in patient outcomes that are related to laboratory service delivery in the various settings; and

- identifying strategies for identifying and collecting data that measure changes in quality of patient care as it relates to changes in cost, availability, and quality of laboratory services.

Following is a summary of the discussions that occurred amongst the 30 participants who attended the workshop. As noted in the Institute guidelines, this summary does not represent a consensus document, but does enumerate the significant points raised in the session.

A goal of the Workshop was answering the questions:

> "What can be done within our present system of delivering laboratory services to improve patient outcomes?"
>
> "What can be done in the future to design better systems to achieve higher quality laboratory services?"

Kathleen C. Aller presented an overview discussion of "Health care Information Systems: Foundations for Future Research" that described the present state and future direction of computerized information in today's health care system. William M. Tierney, M.D. followed with a talk on "Deploying Information Technologies for Better Laboratory Use and Patient Outcomes: A 20 Year Odyssey at One Academic Medical Center" that showed how a unified medical information system can

directly affect changes in the practices of patient care delivery. Christine Diehl spoke on "Hospital Systems that put Patients at Risk" which addressed strategies that a large health care delivery system, Columbia/HCA, is implementing the laboratory area to insure cost-effective quality laboratory medicine. Jay M. McDonald, M.D. closed the formal session with a talk on the "Role of the Laboratory Professional - New Opportunities," where he described the extended laboratory of the future and how it reaches out across laboratory disciplines and testing locations using integrated computer systems.

We noted that the opportunity exists for laboratory professionals to move outside both the physical and metaphysical walls that have isolated them and become an integral part of the health care delivery team. To achieve the required paradigm shift, laboratory professionals must move from their present reactive mode and take a proactive position in the health care community.

Our discussion group felt a need to clearly define the role of the laboratory professional in today's system. From that definition, they could then develop a vision of future roles. Changes required in moving toward the future role would help define a future research agenda.

Present Role of Laboratory Professionals:

1 . Run Laboratory Tests: Today the laboratory professional has a direct role in the actual performance of tests. However, the role extends much further than the production of a result. It involves the development of quality control and quality assurance systems that maintain a continual level of performance required by co-workers in the health care system.

2. Deliver Results:. The number of laboratory tests ordered within the health care system has led to the development of expertise within the laboratory community in the computerized delivery of medical information. That knowledge has placed laboratory professionals in pivotal positions in the computerization of health care delivery.

3. Selection of Tests: Laboratory professionals directly and indirectly influence the selection of tests made available to clinicians. They directly influence the selection of tests when they serve in the consultant role, which can occur directly on request by a clinician, or indirectly through computerized guidelines such as those developed by Dr. Tierney. They indirectly influence the selection of tests by making readily available to the clinical community only those tests that they feel are effective.

4. Convert Data into Information:. A laboratory result in itself is simply data and its utility lies in the conversion of that data into information that the clinician can use. A simple way of converting the data into information is through the use of normal or reference ranges established by laboratory professionals and then used by clinicians as interpretative guidelines. More complex conversion tools include reflex testing algorithms that

can automatically triage laboratory work-up in both a time and cost-effective fashion, and integration of laboratory and other clinical data, especially from the pharmacy, to warn of or interpret changes in a patients condition. While the complex conversion tools can have manual implementation, they generally involve automated, computerized systems, sometimes linking multiple clinical areas.

5. Technology Assessment: Assessment of laboratory technology is a key role that also encompasses development and implementation of new technologies. Technology encompasses that used for performance of laboratory tests, delivery of results, and conversion of data into information.

6. Managing the Shift to Managed Care: Laboratory professionals play a key role 'in maintaining access to quality laboratory tests as our health care systems shift into it into a managed care environment. It was observed that in many locations, Medical Technologists were more aware of the implications of the shift to managed care then the Pathologist/Laboratory Director.

Future Roles of Laboratory Professionals:

1 . Determine Clinical Utility and Appropriatenss: Many in the health care industry feel that laboratory tests are used inappropriately, which encompasses both under- and over-utilization of tests. Workers in laboratory medicine will serve in a leadership role in investigating the proper clinical use of laboratory tests as testing moves into more diverse locations.

2. Serve as Consultant on Selection and Interpretation of Tests: As health care resources become more limited and possibly more restrictive, rapid selection of the proper laboratory test or test strategy will become increasingly important. The laboratory professional will move from the passive role they now play in the direct laboratory work-up of a diagnosis and become an active player in the test selection process. They will achieve this goal through both direct consultation and by their influence on programmed ordering systems that will exist in either written practice guidelines or computer programs.

In this role they will help to optimize resource utilization in the diverse testing locations of the future. That movement will require careful management to insure limited health care funds are put into optimum use. The laboratory profession should be in a position to help decide what tests are done at what site for what purpose.

3. Assess Technology, Conduct Health-Services Research: To achieve these future roles, the laboratory profession must expand the current research efforts and understand laboratory processes better. These new research efforts must coordinate with existing efforts in the emerging area of health-

services research. Coordination must exist in terms of the manner in which the research is conducted and the topics studied. Joint projects with peers in other medical disciplines must occur on a regular basis.

4. Manage Testing in Non-traditional Settings:. Future laboratory testing will no longer occur within the physical walls of a laboratory but will be done in many diverse locations. Some of these sites include point-of-care testing in hospital or home locations, increased self-testing by patients, and physician office laboratories, especially those of large clinics. The laboratory professional must be prepared to direct and manage the quality of testing in all sites and understand the differing performance needs of tests in non-traditional locations.

5. Manage Information System: Laboratories were one of the first non-financial areas of a hospital to embrace computers. That early experience has placed the laboratory professional as the key person in many institutions to work with the expanding needs of health care information. They will serve or lead the infrastructure now being developed toward the universal electronic record envisioned by our panelists.

6. Quality Assurance in Non-laboratory Areas: Organized quality assurance programs have always had a key role in the delivery of laboratory medicine. The understanding laboratory professionals have in this process makes them a logical leader in the quality assurance programs in other health care areas.

Suggested Strategies and Methods

To achieve the future goals the laboratory profession must look into four areas: Health and Laboratory Information Systems; Assessment (analytical) Issues, Organization, and Guidelines. Research studies are required in all these areas to allow for an orderly evolution of the profession.

Health and laboratory information systems must integrate both vertically (across health care systems) and horizontally (within a health care system). To achieve these goals, we must increase our research in standardization of codes used by various systems and the grammar that defines the linkage of the codes. Of particular importance is the introduction of a Universal Patient Identifier which will uniquely identify a patient across all health care systems. These systems must have intelligence that will enable them to link various parts of the patient record and even to research literature. That intelligence should express itself in usable patient care guidelines.

A principal goal of near term Laboratory Focused Health Systems Research should be analytical and focus on the areas of assessment and data gathering. Our lack of even fundamental data in many areas of laboratory medicine leads to the high priority of these types of studies. We must start to aggregate existing data found in the dispirit computer systems found throughout our health care system. From these data we must develop ways, using the techniques developed in other areas of health services research, to determine the appropriateness of testing under various scenarios and the value

of testing as it applies both to individuals when they enter the health care system and the population to provide adequate information required by the public health system. Studies evaluating tests should include issues relating to clinical hazards, and benefits. Patient satisfaction must become an important consideration in evaluating tests, especially when alternate non-traditional testing sites, such as the home, are considered. All of these research topics must be studied using scientifically valid impact and process measures.

Delivery of laboratory medicine will change in the coming years and the profession must be prepared for that change. We will see changes in organization, both within an institution and throughout a health care delivery system that will reorganize the role of the laboratory. Laboratorians will now work more directly with providers and patients providing care instead of from the distance they now operate. This care will be delivered through many diverse locations including the traditional hospital and reference laboratories, point-of-care sites within institutions, home testing, self-testing, and extended care facilities. Our relationships with the vendors and manufacturers of our tools and supplies will change and develop into a closer partnership as both the economics and needs of the profession change. Compensation within the profession will change away from a cost-per-test basis to accommodate the changes developing between the deliverers of health care services and those paying for it. We must be prepared to monitor these changes and make sure they achieve the goal of enhancing efficiency.

Much of the future systems will derive from implementing care guidelines. It is felt that done carefully, these guidelines will improve the delivery of care. Their development must include all areas of medicine, including the laboratory, as part of the core team. Teams developing guidelines should realize that medicine is practiced differently and successfully in many areas. Differences derive both from local practices and the differing philosophies of training programs. Any guideline that does not allow for local adaptation will fail to be adopted. Teams must also realize that practices change and the guidelines must also change to be successful. Hence, they must include monitoring steps to assure compliance and determine the need for change.

We expect the changes that will occur to derive from the development of multidisciplinary teams. Within a health care delivery system, these teams will include members from all areas of medicine. Within the profession of laboratory medicine, these teams will come from partnerships formed between laboratorians and laboratory equipment manufacturers, managed care organizations, pharmaceutical and other medical device manufactures, and academic medicine. The work of these teams will require funding from a variety of sources including the government, medical care payers, managed care organizations, and private funding from sources like foundations. All have a need for results from these research studies and in today's world of limited funding must be willing to share in the development costs.

Our discussion concluded with the clear message that laboratory focused health services research was required to move the profession forward. To better understand how to conduct the research programs, it was felt that we needed to introduce the principles of health services research into the training of laboratory professionals.

Introduction of that training would make the acceptance of the research programs by laboratorians more acceptable. Training will also help start the required movement by laboratorians outside of their traditional walls and into the total health care delivery system.