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Rationale for Cost-Effective Laboratory Medicine

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ESCALATION OF HEALTH CARE COSTS

Total Health Care Expenditures

The U.S. health care expenditures exceeded $800 billion in 1992 (33), and health care costs are increasing at an annual rate of 15% (13). Interestingly, physicians control up to 80% of these costs (64). Between 1965 and 1979, total annual expenditures for health care in this country increased from $40 billion to $206 billion per year, and this represented a change from 5.9 to 9.1% of the gross national product (11). By 1985, health care costs represented 10 to 12% of the gross national product (59). It has been predicted that, although health spending may be slowed, it will continue to grow both relatively and absolutely with respect to the rest of the economy, and the country is expected to reach the trillion-dollar level in health care expenditures by 1995 (33). It is also anticipated that health care costs will reach 15% of the gross national product by the year 2000 (64). If the present course is maintained, the United States will have to identify another trillion dollars to spend on health care between the mid-1990s and the turn of the century. It has been speculated that, based on recent and projected rates of economic growth, a second trillion dollars to support the nation's health care system during the last half of this decade will not be available since such an expenditure would represent an average yearly health care cost of $30,000 per family of four (33).

Laboratory-Related Expenditures

Laboratory testing and its associated costs to patients and third-party payers have increased substantially since federal regulations were enacted in the mid-1960s, with growth rates varying in different sectors of the market. Laboratory costs account for nearly 10% of overall health care costs in the United States and exceeded $30 billion annually in 1985 (59) contrasted with $12 billion in 1975, representing a 15% annual growth rate for laboratory testing (15). Approximately half of laboratory expenditures is generated by hospital laboratories, with the remainder generated in approximately equal proportions by commercial private laboratories and physician office testing (59). Laboratory testing has a greater role in acute hospital patient care than in ambulatory, nursing home, or mental health care. This is illustrated by the observation in one acute tertiary-care hospital that clinical laboratory test charges averaged 24% of the total hospital bill of patients coming to autopsy in 1984 compared with the national laboratory test cost average of 10% of overall health care costs (59).

The costs of clinical laboratory services are considered to be an important contributor to the general inflation in medical and health care costs during the past 20 years, resulting in a heightened concern with regulating clinical laboratories and

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controlling unnecessary costs associated with laboratory testing. Medical care financing provided by the Social Security amendment of 1965 led management consultants to predict market growth in laboratory testing, which encouraged entrepreneurs to initiate or expand clinical laboratory ventures (2). It was certainly reasonable to anticipate that there would be an increased demand for laboratory tests since such a large proportion of the population had access to insurance coverage. The cost of laboratory services in 1975 increased by 13% contrasted with a 10% increase for all health care services and a 7% increase for the economy (11). Half of the laboratory cost increase in 1975 was the result of increased test cost, and the remainder was due to increased utilization and new services. Because a patient is insured, tests are thought to cost the patient nothing. In fact, increasing medical costs are incurred by the patient in the form of higher insurance premiums. It has been suggested that elimination of unnecessary laboratory tests could represent a major contribution to efforts to contain health care costs. However, other observers have advocated a more cautious interpretation of the cost information. Schwartz noted that, although the use of "little ticket" tests did rise from 1950 to 1970, since the early 1970s standard laboratory tests have not been used with increased frequency or contributed to rising costs (56). Instead, he places the blame for rising costs on new procedures and high-technology care. Others caution that any valid economic analysis of clinical laboratories must make a clear distinction between laboratory charges and laboratory costs since laboratory pricing policies are not related solely to cost or to services offered (2, 15, 41). This price/cost disparity can be traced directly to hospital budgeting methods that use the clinical laboratory as a profit center to support unrelated deficit-producing hospital operations, and this may obscure inefficiencies that may exist in both cost centers. These hospital as well as private clinical laboratory accounting practices have had a profound effect on the development and management of clinical laboratories since revenues are highly leveraged relative to true laboratory costs, leading to large changes in gross revenues following modest increases in work load or actual costs. This situation is a disincentive for the implementation of more economic use of laboratory services.

The Evolution of Health Care Spending

One analysis of the destabilization of health care in the United States concluded that a combination of multiple trends and forces destabilized the three foundation blocks of the established health care system (32). These included the nonprofit community hospital, physician dominance in therapeutic decision making, and cross-subsidization of the health care of the poor by providers. According to Ginzberg (32), the destabilization process had already begun by the mid-1960s when the federal government enacted Medicare and Medicaid reforms. The two important factors that upset the status quo, but were insufficient to destabilize it, were a larger supply of physicians and more extensive health care insurance. It was the Medicare-Medicaid reforms that vested the aged and indigent populations with the ability to pay for medical services, thereby unleashing a number of forces that precipitated the process of destabilization. Normal economic constraints that might have reduced price inflation and excess use of the system were eliminated. In hospitals, third-party payments rose from 77 to 91% of total costs, thereby reducing the preoccupation of trustees and hospital administrators with financial matters and enabling nonprofit hospitals to sever their relationships with philanthropic sources that had funded a large portion of capital purchases. Ginzberg also notes that an often overlooked consequence of the increased cash flow was the diminished interest and power of the boards of trustees, thereby weakening a former major source of strength from within local communities. The for-profit hospital chain emerged following implementation of Medicare and Medicaid and the associated perception of virtually unlimited health care needs, and some have predicted that the health care system will be dominated by 10 to 20 "megafirms" before the end of the century. In the 1980s, competitive forces played an even bigger role in health care as evidenced by the rapid growth of health maintenance organizations, preferred-provider organizations, other forms of managed care, the efforts of businesses to successfully renegotiate their health benefit packages, and the entrepreneurial activities by both for-profit and nonprofit health care organizations. Aggressive marketing and other competitive business methods have been used by both profit and nonprofit providers for the express purpose of expanding a provider's market share and increasing revenues (52). Not surprisingly, commercialized health care leads to increased consumption concomitant with increased expenditures. The establishment of professional standards review organizations and certificate-of-need legislation in the early 1970s along with the establishment of prospective payment for hospitalized Medicare beneficiaries in the early 1980s signaled the more aggressive role of the federal government in health care. The destabilization process was facilitated by the institution of the prospective payment system (PPS) in conjunction with a growing excess of both physicians and hospital beds (32). As a result of rapidly declining patient census, many hospitals joined one of the large chains, and the chains claimed membership encompassing one-third of all nonprofit hospitals. Not surprisingly, many physicians entering practice discovered an extremely competitive market along with escalating malpractice insurance costs, and many ultimately selected salaried employment in lieu of establishing a private practice. Physicians were further restricted by the rules of peer review organizations and treatment guidelines promulgated by hospitals in response to prospective payment (32).

An interesting macroeconomic perspective on health care spending was offered by Getzen in 1989 (30). The crux of his article is that the factor that controls health care expenditures is available income rather than needs, new technology, federal health care regulations, or managed care. Instead, according to Getzen, these other factors impact only on the distribution of dollars among various services or institutions without substantially altering the aggregate expenditure for health care. Macroeconomic effects are often overlooked because lags in the impact of booms or recessions can make it difficult to identify the cause of change in health care spending. A recession or boom takes several years to affect spending, with a peak effect at 4 years, and has a lingering effect for more than a decade. Adjustments for inflation have also contributed to a preoccupation with higher prices rather than increased wealth as the reason for increased spending. To substantiate the role of income in health expenditures, Getzen points out that real health care spending, adjusted for inflation and population, increased continuously from $259 per person in 1929 to $2,233 per person in 1987 except for the years 1929 to 1935 which coincide with the Great Depression. He attributes 75% of the rise in health spending to the rise in per-capita income, with each 1% rise in income corresponding to health spending increases of 1.6%. Inadequately identified factors other than income cause an additional growth in expenditures of 1% per year. The fact that the medical care price index has annually

risen approximately 2% faster than the consumer price index is a reflection of a choice made by an increasingly wealthy country to spend more on a higher-quality and -intensity health care system. The portion of the gross national product spent on health care, the increase in income, and inflation all contribute to rising health care spending even though inflation reduces spending in the short term since health care price adjustments generally lag behind other prices in the general economy. However, the effects of inflation are more immediate than those observed with changes in the gross national product. Therefore, in spite of the fact that the gross national product is the primary factor determining the magnitude of health care expenditures, inflation is more important in predicting the situation in the short term, such as a year. Hospitals benefited in the short term from the inflation triggered by the 1978 OPEC oil crisis since the lag in health care price increases permitted reimbursement to rise faster than costs. The tight macroeconomic policies of the 1980s successfully reduced inflation, perhaps too successfully, causing the consumer price index to fall to a 20-year low of 1.8% in 1983 and health care costs to rise faster than reimbursement. Although other nations reduced their health care spending as a result of the oil price crisis, the United States talked about making dramatic cuts but in reality made only modest reductions and shifted the cost burden to patients. However, this should not be unexpected since, as Getzen points out, there have been no true reductions in health care expenditures since the depression years. Furthermore, it is unlikely that spending will even be held constant for more than 1 or 2 years.

The Health Care Cost Quagmire

There is a plethora of explanations for the current state of health care spending in the United States. Whether one ascribes the excesses to bureaucratic systems, waste and inefficiency on the part of health care workers, industrialization and commercialization of medical care with concomitant increased consumption, new technology, public expectations and overconsumption, open-ended third-party payments, or physician compulsiveness and insecurity, the cost of health care has exceeded what the public is willing to pay for, especially in view of the growing realization or perception that increased resource commitments have only marginally improved the gross indicators of health (43, 54, 55). McGregor states that the major problem with health care is its success, meaning that, each year, medicine has greater capabilities with attendant cost increases that will negate any cost savings made to conserve the relatively constant health care resources (43). As a result of the increased expenditures for personal health services, public funds for other initiatives that might significantly improve the health of Americans, such as public health, education, research, and planning, have been systematically reduced in federal budgets (54).

INCREASE IN LABORATORY TEST UTILIZATION

Increasing Laboratory Test Use and Cost

Although many factors contribute to and compound the escalating health care cost problem, the increased utilization of health services, especially diagnostic services, is considered to be one of the most important elements and is a cause for justifiable concern (11, 60). About half of the overall increase in health care spending during the 1960s was the direct result of increased utilization of medical services and not inflation of charges (21). Charges for ancillary services, which include laboratory tests, represent about half of the total bill for hospital care and are increasing annually at a rate of about 15% (38). Expenditures are rising as a result of the increasing application of both old and new technologies whether they are beneficial or not (1). In New York, with a population of approximately 1.3 million people in 1973, Medicaid purchased approximately 3.8 million laboratory tests, and this represented only a fraction of the total tests ordered (49). Even more disconcerting is the accumulating evidence that approximately 5 to 30% of ancillary service use may be unnecessary and noncontributory to patient care. Depending on the specialty and related prejudices of the individual who performs the chart review, various investigators have reported that between 26.5 and 98% of laboratory tests are unnecessary (50, 73), and in institutions, laboratory costs have increased significantly more rapidly than the costs of other hospitalized patient care functions (36). For example, it has been reported that in the 1960s and 1970s there was a marked increase in laboratory use by physicians, with house staff actually using only 5% of the laboratory test data for the prognosis or management of a patient's clinical problems (53). Some authors have expressed the opinion that unnecessary medical care expenditures are an inherent part of the American medical system and grow as the system expands (1).

From a microbiology laboratory perspective, there is a direct relationship between work load and the number of technologists needed to perform it as a result of the general lack of automation of the clinical microbiology laboratory. Microbiology is an expensive laboratory service, because it is labor-intensive, and technologist salaries generally account for 50 to 70% of a laboratory's operating budget (23). Repetitive daily cultures from a suspected site of infection rarely contribute useful information for patient management. Excessive numbers of blood cultures, daily sputum cultures from patients without signs of pneumonia, daily cultures of various drainages, or cultures of superficial patient material are some examples of overutilization of the microbiology laboratory. At one hospital the average patient had 6.1 bacteriology tests per admission, with 122 tests associated with one patient and 24 urine cultures from another patient (36). In this study, the typical pulmonary patient had an average of 16 sputum cultures, 13 blood cultures, and 9 urine cultures.

A multitude of factors contributing to excessive laboratory test utilization has been described in the literature (1, 35, 49). Beyond the previously discussed broad impact of the Medicare-Medicaid enactments and attendant reimbursements upon health care access and spending, responsibility for excessive laboratory test use can be assigned primarily to the following four groups: practicing physicians, physicians in training, patients, and the clinical laboratory. Each group not only has individually escalated laboratory utilization but has interacted with other factors or groups to compound utilization expansion.

Physician Contribution to Increased Laboratory Testing

Although multiple factors contribute to excessive use of laboratory tests, physicians are the single most important factor in the expansion of laboratory test utilization, which is consistent with the observation that physicians control up to 80% of health care costs (11, 64, 72). Physicians have been shown to overutilize, underutilize, and misutilize health care resources, including the laboratory (46, 50). Underutilization of laboratory services occurs when relevant laboratory tests are not ordered. Overutilization or misutilization of laboratory

data occurs when irrelevant or repeat laboratory testing is ordered or when the test results are ignored.

Physicians order laboratory tests primarily to screen for unsuspected disease, to establish or exclude a diagnosis, to indicate prognosis, to select the most appropriate therapy, and to monitor therapy (46, 51). At one tertiary-care medical center, 60% of tests are performed to monitor therapy (46). Tests are also ordered to confirm previous results and for medicolegal purposes. Additional test requests can be justified if the results enhance diagnostic accuracy or improve patient management. Test ordering patterns may change as a result of using additional existing tests for patients with the same problems, using the same tests for a wider range of clinical problems, or introducing new tests (60). Test ordering practices vary substantially among physicians, leading to the conclusion that clinical indications for diagnostic tests are rarely absolute and that other factors weigh in the determination of a physician's test ordering (22).

A litany of reasons for excess laboratory use by physicians has been published, ranging from insecurity to opportunistic motivations. The factors influencing physician overutilization of laboratory services include the following: ease of access to laboratory tests; insufficient knowledge of test characteristics, including limitations; ordering of secondary or tertiary laboratory tests without considering primary test results ("shotgunning"); incorrect interpretation of test results, leading to more tests; use of more than one confirmatory test; screening for the possible presence of rare disorders; ordering of new tests without deletion of old tests from the routine repertoire; reliance on technology rather than rational cognitive problem solving; inappropriate test ordering; generic preadmission or admission testing protocols for all patients; application of routine test ordering protocols in high-volume care areas; reliance on laboratory data to detect clinically inapparent diagnoses or changes in a patient's clinical state; innate curiosity; physician ethic endorsing no rationing of health care; physician role as a patient advocate; physician expectation that each specimen be completely analyzed; physician belief that patients are impressed by the performance of numerous tests; test ordering to allay patient concerns; need to completely "work up" a patient to satisfy or impress peers or supervisors; fee schedules that reward physicians for performing tests and procedures; lack of concern for and knowledge of cost implications of ancillary services; lack of cost impact on the ordering physician; multiple physician involvement in individual patient care; fragmentation of care resulting from subspecialization; medicolegal considerations; and complete documentation as evidence of quality of care (1, 4, 11, 21, 22, 35–37, 39, 48–50, 60). A relationship between laboratory usage and physician age has been demonstrated, with less use associated with older physicians (50). The more obvious explanation for this observation is that physicians gain experience through trial and error, eventually becoming more selective in test ordering. Or it may be that younger physicians are electing to take a more expedient path and order a test rather than deliberate over a diagnostic problem (50). It has been noted that a "blanket requester" who orders unnecessary tests may reduce inpatient length of stay and costs compared with the "traditional selector," who reviews initial diagnostic test results before selecting additional studies (60). Defensive ordering in response to potential malpractice litigation has intensified in response to large medicolegal settlements. However, as pointed out by Overholt, excessive test requisitioning does not protect against liability, since malpractice is usually the result of failing to order tests at the correct time (48). It is the quality of the testing and its timeliness and appropriateness, not the quantity of tests, that is most important. However, this defensive overutilization of laboratory tests will continue to increase unless the public is informed about the magnitude and expense of the litigation problem and the need to place realistic caps on settlements (46).

There is abundant evidence that fee-for-service practice does encourage overutilization of diagnostic services (21, 22). Financial incentive to order tests occurs when physicians operate office laboratories or invest in private laboratories. Physicians have a clear economic incentive to order and bill for tests when test reimbursements exceed test costs. There is evidence that adjustments in payment do trigger physician responses, which may include increasing test demand or altering prices for other physician services relative to laboratory test price charges (22). There is minimal documentation of significant test demand creation by physicians in response to financial incentives. Small amounts of demand creation have been noted in ambulatory settings and none have been noted in inpatient care. In response to the price freeze during the Economic Stabilization Program in 1971, office visits and ancillary services increased in California, resulting in globally greater expenditures than before the price freeze (22). When the price freeze was over, physicians increased charges and reduced volume. Another example of government price control and resulting physician response occurred in Colorado when Medicare payment rates were reduced 1%, resulting in a 0.61% increase in intensity of medical services and a 0.52% increase in laboratory testing (22). It has also been shown that Medicare and Medicaid payment ceilings for office visits and tests increase the frequency of tests. When the relative payment rates for different services change, physicians tend to substitute more lucrative services for less profitable ones. For example, when payment rates for office visits are reduced, physicians replace time previously spent with patients with laboratory tests (22). Raising a test price may or may not increase test volume since some physicians might elect to maintain or even reduce demand in conjunction with a price increase since an increased price enhances the physician's income even in the absence of a net gain in volume. In contrast to the fee-for-service practice, physicians in managed-care arrangements have a financial incentive to contain health care costs. A number of mechanisms have been developed and implemented to detect and curb unnecessary service use, including professional standards review organizations. An interesting dilemma is who should pay for unnecessary medical services: the patient, the doctor, the hospital, and the third-party payer are possible candidates. One proposal suggests that the physician should share financial responsibility for overutilization of services (21). Up to now, there have been insufficient incentives for physicians to seriously control the abuse of laboratory resources. Unless such incentives are identified and implemented, physicians will continue to make inefficient use of the laboratory and to play a major role in maintaining disproportionately high laboratory costs.

Physician Education Role in Increased Laboratory Testing

A major component of the medical education process has been the self-education segment in which each medical student and resident accumulates his or her own data base to draw upon in clinical decision making. Although this information is also obtained from teachers, reading, peers, and observation, confidence in the data base is built primarily through actual use. A number of undesirable features of this self-education process have been cited (15). This approach supports the development of a pattern-recognition use of laboratory data

rather than a statistical frame of reference. House staff think less and rely more on test results than on clinical judgment. Individuals resist eliminating obsolete laboratory tests since this means altering the accumulated data base. Also, there is the realization that the vast data base needed for optimal use of the laboratory has exceeded the capabilities of most physicians, leading to the potential for serious omissions and misjudgments. Finally, the process is expensive. Expenses are accrued for activities other than the pursuit of new knowledge. Some university teaching centers emphasize complete patient workups, and the house officer must submit to teacher demands (35, 39, 49). Other residents believe that their peers or teachers will be impressed if all possible testing has been performed (39). Frequently, house officers fail to determine what tests have already been ordered, resulting in duplication of services (39). Additionally, the systematic reduction of laboratory medicine in many undergraduate medical education curricula has contributed to a general lack of knowledge regarding laboratory test methods and associated costs. This has been compounded by the lack of involvement of medical students and residents in the laboratory (46). Although the current medical education process has contributed to the escalation in laboratory testing, medical education may be one mechanism to implement effective laboratory utilization (72).

Patient Role in Increased Laboratory Testing

The public expects a high standard of health and demands that it be delivered (11, 22, 60). This expectation has resulted in the development of new tests and the extended application of established tests to more patients (60). One explanation for this growth of unnecessary medical care is the American belief that every problem has a solution, frequently a technological one (1). Patients may demand test performance regardless of price as a result of broad insurance coverage and the need for reassurance (22). However, in general, the contribution of patient factors to increased laboratory testing is perceived to be insignificant compared with other factors (11).

A portion of the patient-related test increases are justifiable. Factors such as the "case mix" of the patients in a hospital can influence the intensity and variety of testing (11, 35, 60). For example, a high proportion of tertiary-care patients requires more investigations than a simple primary-care population. Likewise, increased testing can also be attributed to increases in the numbers of patients cared for as outpatients or inpatients in certain centers.

Laboratory Role in Increased Testing

Laboratory factors that contribute to overutilization include the impact of scientific advances and automation, logistical conveniences, and laboratory inefficiencies (11, 35, 36, 60). The ready availability of automation and the large quantity of data generated have changed clinical practice from being primarily problem oriented to mainly data oriented. Increasing conveniences, including phlebotomy teams, comprehensive laboratory test requisition forms, and cumulative reports, have made it simple for physicians to excessively use the laboratory. Physicians also overorder tests to compensate for specimens that fail to be collected, are lost in transport to the laboratory, or have a long turnaround time.

Although the laboratory could attempt to contain the rising work load, a number of reasons have been cited as to why laboratorians have been reluctant to address the issue (60). Continuous effort is required to control incoming work load, and many laboratories do not have the personnel resources needed to implement and maintain a work load control mechanism. Other workers do not want to encounter the negative feedback that a critical approach can generate or may assume that all test requests are clinically necessary even though existing data do not support this premise. Another factor that has contributed to the lack of work load control by the laboratory is the existence of the laboratory primarily as a revenue center rather than a cost center. This acts as a disincentive for reducing the number of test requests.

Screening Test Role in Increased Testing

As a result of the technological developments introduced by laboratory medicine over the past three decades, the clinical strategy of applying screening tests to patients without specific clinical indications has evolved (2, 11, 60). One rationale for this strategy is that, by making rapid, economical tests part of an initial examination, the diagnostic process is broadened, leading to a more rapid conclusion (2, 11). Standards of medical practice taught to medical students and promoted by medical practitioners emphasize the analytical approach to disease diagnosis. The use of a broad range of tests to confirm a suspected diagnosis or perhaps reveal a less likely health condition can lead to additional diagnostic efforts which may include more specific test batteries. This approach converts the problem-oriented diagnostic process to a mainly data-oriented process. Several studies have found no difference in the length of hospital stay when groups of patients who underwent screening tests were compared with control groups, although laboratory testing increased in screened groups as a result of repeat tests and led to increased hospital costs of 5% (11, 50). Routine use of screening profiles has increased also in the ambulatory patient population as a means of early, preventive care and provision of baseline laboratory data. Screening profile tests can produce unexplained, abnormal results that generate additional work even though the data may represent only extreme values in healthy individuals (60). The cost benefit of admission testing, test batteries, and other screening panels has not been demonstrated. However, screening tests have adversely affected the clinical approach and have contributed to the production of a mass of data that may obscure important results (11).

Every unnecessary diagnostic investigation, including mass screening, places a patient in danger of incurring what is known as the Ulysses syndrome (11). This literary descriptor is a reference to the series of needless trials and tribulations experienced by Ulysses when he took a detour on his way back from Troy after the Trojan War. After 20 years, he finally returned to his home island of Ithaca where his family awaited him. In this syndrome, a healthy individual has the misfortune of encountering a false-positive result from a screening test profile initiated as the result of a routine health examination. Like Ulysses, the patient is healthy at the start and must make an unnecessary, long, dangerous detour through the medical arena before returning to the point of origin.

Although the physician is responsible for ordering screening profiles, the laboratory community has provided the availability of profile testing. Even in the absence of actual cost savings, the combination of several tests in a single panel can be used as a marketing ploy by a laboratory (2). The test panel may be marketed as an economical health screen or as a unique diagnostic tool. The aggressive commercial orientation of numerous laboratories has led to the conversion of the laboratory industry from one concerned with professionalism to one dominated by marketing strategies and profits (2). Incentives exist for many laboratories to continually escalate sales

and thereby increase profits. These business practices have created problems for the health care community and have adversely affected efforts to contain costs, especially in view of the commercial laboratory's role in generating test demand which is invisible to the patient consumer.

Lack of Beneficial Outcome Associated with Increased Laboratory Testing

A number of studies have failed to establish a beneficial relationship between an increased number of test results and various outcome indicators. One investigation determined that a 27% increase in laboratory tests in patients hospitalized with diabetic ketoacidosis failed to influence the outcome of care as measured by length of hospital stay (36). Significant variations in the application of laboratory services to a prepaid health plan population did not affect the efficacy of patient management (49). Daniels and Schroeder (17) found a marked degree of variation in laboratory utilization for ambulatory hypertensive patients, and the cost variation for laboratory tests was 20-fold. This study failed to demonstrate that increased laboratory testing is associated with more efficient patient care, and moreover, higher laboratory costs had a negative correlation with clinical outcome, as measured by blood pressure control, suggesting that less competent physicians tend to order more laboratory tests. In one institution, a 20-fold increase in the number of laboratory tests did not significantly alter the number of hospital deaths or the length of stay during a 30-year period (53). A teaching hospital in Canada identified increased costs, as a result of an increase in testing, in the absence of an improvement in the efficacy of care (50). In two institutions, the numbers of laboratory tests per patient for a specific test were reduced 25 and 67%, respectively, without adversely impacting patient care (50). Another study showed that 30% of the patients with a normal biochemical profile on admission proceeded to have two additional profiles during the same admission, and none of the results provided data necessary for diagnosis or management (73). The ample available evidence in the literature does not support a positive association between the extent of laboratory use and either clinical productivity or outcomes of care. Many requests, including repeat testing, are not clinically necessary or beneficial. Patterns of laboratory usage frequently do not correlate with the needs of the patient, and physicians who overutilize the laboratory are simply more expensive rather than more efficient.

Although the increasingly wasteful use of laboratory resources by physicians has contributed to the escalating cost of health care without concomitant benefits, increased laboratory testing also has had serious adverse consequences on several noneconomic aspects of health care. It has been shown that the frequency of iatrogenic complications in hospitalized patients is proportional to the number of tests and procedures performed (36). Excessive demands on the laboratory can increase the frequency of laboratory errors, leading to results that confuse rather than clarify a diagnostic situation, and may adversely affect the patient (36, 39). Another detrimental effect of escalating laboratory testing is the production of excessive information which inundates physicians, leading to information overload and thereby obscuring crucial information (50). Therefore, excessive information can be a liability to patient care rather than an asset, and less testing can be more beneficial.

IMPACT OF NEW TECHNOLOGY ON COST

Emergence of New Technology

Technology has been rapidly introduced into laboratory medicine and other services during the past two decades. This has not only altered the ability of medicine to diagnose and treat disease but also changed the public's expectations of health care (27, 28). The concept of technology includes any new procedure, regardless of whether or not instrumentation is involved (68). Technology can be characterized as new, more scientifically complex, and more expensive in comparison to "nontechnology" (43). Westlake (68) cites the following seven types of applications of technology in the clinical laboratory: (i) performance of a new procedure routinely, (ii) performance of a new procedure in specialty laboratories only, (iii) improved service as a result of decreased turnaround time or some other criterion, (iv) cost reduction in an existing service, (v) simplification of test performance, (vi) increased accuracy or precision of an existing procedure, and (vii) enhanced management decision making.

Economic Pros and Cons of Technology

Divergent opinions regarding the economics of laboratory technology exist. One perspective is that technology increases the total costs of providing health care and that the benefits do not equal the expense accrued as a result of technology (6, 28, 40, 43, 65, 68). However, it is difficult to determine or quantify the benefit of technologic change and assign dollar costs. One approach has been to determine the relative share of total hospital costs or total health costs allocated to a particular discipline and then attempt cost-benefit analyses (65). It has been noted that cost justification of new technology based on reduced staffing may be erroneous. The labor-saving potential of a new technology may be overestimated by the manufacturer or laboratory director, or other costs, such as reagents, maintenance, or replacement equipment, may negate any savings realized as a result of labor reduction and, therefore, must be included in the financial calculations (6, 18). McGregor argues that the increased costs associated with technology are proportional to the success of each innovation and that the new technology and its attendant costs permit the treatment of many diseases that formerly were nontreatable (43). An opposing point of view regards technology as the most economic mechanism to enhance both service and quality and offset the costs associated with these improvements through increased productivity (11, 14, 55, 65). Since labor and fringe benefits account for approximately 70% of hospital costs, an industry perspective cites technology as one of the few means to control increasing health care costs as a result of increased productivity (28). In 1980, less than 5% of the laboratory operating budget was allocated to lease and depreciation of equipment and buildings in contrast to 5% of the gross national product and 10 to 15% of industry budgets being invested in depreciation and lease (28). An example of how automation can lower the cost of hospital services was given for a hospital in New York City that was able to perform 2,213,000 laboratory tests in 1975 for $0.51 per test in contrast to 214,000 tests in 1965 for $2.63 per test (28). The laboratory costs remained essentially unchanged if 1975 dollars were normalized to 1965 dollars, but ten times the number of tests were performed in 1975 with a 5-h decrease in turnaround time. However, although data suggest that technology has enabled an increase in test demand to be almost offset by increased productivity, the trade-off may not be cost-effective unless the new technology offers more information, since an increase in test availability may induce

increased test ordering, causing an increase in the laboratory cost per patient admission (65).

Cost Containment of New Technology

The rapid emergence of new technology has frequently resulted in a new test receiving immediate acceptance and uncritical application among the fanfare of promotional activities and initial glowing reports (43, 48, 51). Often there has been little concern for a new procedure's or system's relative effectiveness or benefit (28), and this has been stimulated by a health care system that insulates patients from costs and provides incentives to physicians and hospitals to use more technology (55). However, laboratorians have become concerned that some of this new information may not be useful in patient management (19). Laboratory tests have a predictable life cycle, beginning with initial glowing reports followed by enthusiastic acceptance, widespread use, disillusionment, and gradual realization of appropriate application (51). It has been speculated that this cycle is simply a logical extension of predictive value theory since the discriminatory value of a test is a function of its sensitivity and specificity and of the prevalence of the disease in the study population (51). The microbiology laboratory has shared in the technologic advances experienced in the other areas of the clinical laboratory and has found that conventional methods continue to be used, even when replaced with a new procedure, until the predictive value of the new method is completely understood (6, 11). As a result, the technology pool is continually expanding along with exhaustive laboratory test requisition forms and multiple bits of laboratory data that frequently yield conflicting results. Bartlett (6) cites bacterial antigen detection as one example of overenthusiastic application of new technology. When both counterimmunoelectrophoresis and latex agglutination were first introduced, clinicians insisted that the procedure be available 24 h a day, because early reports touted each method's sensitivity for the early detection of bacterial meningitis. However, Gram-stained smears of cerebrospinal fluid continued to be ordered and performed. After several years, many laboratories collected data that indicated that bacterial antigen detection was seldom more useful than the Gram stain in the detection of untreated bacterial meningitis. Additionally, the predictive value of the latex test for the diagnosis of meningitis in untreated patients with Gram stain-negative, normal spinal fluid has not been established (6). Although new molecular technologies have the potential to enhance the speed, sensitivity, and specificity of microbial detection, these methods will tend to increase rather than decrease costs, especially if they are broadly implemented.

New technology is a major cost containment problem, and more control must be used to moderate initial overenthusiastic applications and utilization. Selective implementation of technology, in conjunction with barriers to limit access to a new test, has the potential to save health care dollars by increasing productivity concomitant with controls on demand (65). In view of the increased costs associated with new technology, it is essential to determine the clinical usefulness of the information yielded by the new method and the accuracy and interpretation of the results (5, 19, 28, 42, 60). Ideally, new technology should be implemented only when its benefits to society outweigh its cost (28). However, it is frequently difficult to evaluate the value of new technology when it first becomes available. It has been proposed that it might be preferable to determine whether a specific technology is effective or achieves improvement rather than attempt to balance cost versus benefit since laboratory data have an indirect relationship to patient outcome and there is an insufficient data base for comparison (68). As with most situations, technology in moderation is probably the most effective strategy, including targeting a technology for specific niches where it is more clinically useful and economical than conventional technologies.

EFFORTS TO CONTAIN COSTS

Overview of Cost Containment

There is virtually universal consensus that the health care system in the United States is too expensive and that costs need to be limited. Similar to health care costs in general, clinical laboratory expenditures have increased rapidly as a result of increased utilization and inflationary trends within the national economy. Furthermore, the competitive market that has developed within health care has contributed to the increased consumption of health care services by the public and to the expansion and duplication of expensive services. Numerous options have been exercised to attempt to constrain the spiraling costs.

Ideally, any cost containment measure should maximize benefits and minimize harms (8). As illustrated by Donabedian, there exists a point at which an increase in expenditure yields diminishing returns with respect to benefit, and the additional cost is not justifiable (8). However, the measurement of benefits and costs assumes some standard for comparison. For cost analysis purposes, benefits can be defined as the dollar amount that individuals are willing to pay for the positive outcomes of a specific procedure, and costs are the dollar amount expended to obtain the procedure (34). Defining the costs associated with a procedure can be quite complex. Costs may include not only the cost of the procedure but also time and transportation of the patient, pain associated with the procedure, cost of treatment of individuals with true-positive results, and costs associated with false-positive results. If the benefits exceed the costs, a procedure can be provided and financed in such a manner that society is better off with the test than without it.

The strategies to contain escalating health care costs have ranged from individualized physician education programs to government intervention. Some institutions have reported significant cost reductions by combining numerous strategies to constrain costs (50). Third-party payers have attempted to control their costs through diagnosis-related groups (DRGs), managed care, incentive systems, and increased coinsurance and deductibles (52). However, economic pressure on hospitals and physicians has had limited success, because services have been simply shifted to private physician offices and outpatient facilities where there are fewer cost constraints. In fact, threats to provider income have served to increase marketing efforts to preserve existing revenues. Government regulations have increased the costs of operating clinical laboratories concomitant with reductions in laboratory budgets (19). The standards and regulations promulgated by voluntary and government inspecting and accrediting agencies need to be reviewed to determine whether each rule directly contributes to improved medical care and whether the value received equals or exceeds the cost (45). Clearly, the time for clinical relevance is nigh, and resources can no longer be used for procedures of dubious value, including new technology or duplicative costly services (31). Some experts are hopeful that continuous quality improvement may offer a potential mechanism to eliminate nonessential health care practices since cost

reductions of 20 to 40% have been reported in industry as a result of continuous quality improvement (8).

Prospective Reimbursement and DRGs

By the mid-1970s, escalating federal health care expenditures had become an important political issue (6). The conclusion had been reached that the post-Medicare era had resulted in greater spending with minimal incentives to improve labor or hospital efficiency since any utilization controls or increased productivity served only to diminish third-party payer reimbursement, which was cost based (10). Beginning in 1980, a succession of changes were made in the Medicare and Medicaid reimbursement policies to curb utilization and increase efficiency (6). The Omnibus Budget Reconciliation Act of 1980 included Section 916, which placed a cap on allowable hospital laboratory fees, thereby creating incentives for physicians to perform office laboratory tests. The Tax Equity and Financial Responsibility Act of 1982, the Prospective Payment System (PPS) of Section VI of the Social Security Amendments of 1983, and the Deficit Reduction Act of 1984 have dramatically reversed the incentives for managing hospital resources (59). The Tax Equity and Financial Responsibility Act established maximum reimbursements for Medicare inpatient services, and PPS defined a complex system of DRGs to be used for prospective reimbursement based on diagnosis. The Deficit Reduction Act enacted an outpatient laboratory test fee schedule for Medicare and Medicaid participants and created a Medicare system that indirectly pays for laboratory tests as part of a complete hospitalization reimbursement package (61). These pieces of legislation specifically target laboratory cost reduction as a consequence of increased test ordering and laboratory billing. Whereas a cost-based, retrospective reimbursement system provides little incentive to contain costs and physicians generate additional revenues by providing more complex services, a prospective reimbursement system with DRGs contains incentives for cost containment. A hospital with costs below the predetermined, allowed payment for a particular DRG receives the entire allowed payment and a hospital that exceeds the allowance must absorb the loss. In addition to federal efforts to control rising health care costs, state legislatures and the private sector have tried to curtail expenditures (38, 55). Blue Cross of Massachusetts and the Massachusetts Hospital Association implemented prospective reimbursement and a mechanism to control ancillary service utilization in 1981 (38). Many businesses have noted the Medicare and Medicaid changes and have formulated their own cost-sharing programs to persuade employees to use the health care system more prudently (55).

Implemented in October 1983, the PPS revolutionized Medicare reimbursement to hospitals, and by 1990, two-thirds of health care reimbursements were paid by Medicare or other prospective payment programs (61). Prospective payment has promoted shorter hospital lengths of stay, maintenance of high occupancy rates in hospitals, and cost containment programs that are comprehensive and include multiple strategies (6, 9, 24, 50, 59). Although the government was criticized on the basis that individual patients would receive inadequate care, it has been reported that there has been no measurable decline in the quality of care (50). Patient care has moved into more outpatient and nonhospital settings (59). During the first 8 years of its existence, the DRG system kept price increases below inflation levels, converting the pre-DRG hospital profitability from 15% nationally to an average hospital loss over all DRGs (62). Hospitals are responsible for the care of the indigent, medical research and development, and medical student and postgraduate medical education, and these services must be funded from some source even though Congress continues to reduce research, medical education, and capital expenditures. Hospitals have responded by "cost shifting," which is the passage of DRG losses on to other payers (30, 62). Not surprisingly, DRGs have widened the preexisting payment differential between cost-based and charge-based payers, although some states have minimized cost shifting by requiring uniform payments or freezing payment differentials (62). Hospitals have also learned to maximize reimbursements by classifying patients into the highest paying DRG possible on the basis of symptoms and diagnostic findings and by minimizing the unit cost of hospital services to maximize the margin of profit for as many DRGs as possible (62). Getzen (30) concludes that the major effect of each health care price control has been, and will continue to be, to exert pressure on one part of the health system, thereby shifting expenditures to another part, with minimal actual net effect on the total cost of health care. In the case of DRGs, the reductions in hospital spending were more than compensated for by increased spending in the home health, ambulatory, and long-term care settings, yielding a net effect of zero, with total health care spending continuing to escalate (30). In fact, actual expenditures from 1983 to 1989 were the same as would have been predicted on the basis of dollars spent in previous years and the macroeconomic influences of the 1980s (30). The largest per-capita health care cost increase since 1972 occurred in 1987 as a result of economic expansion that began at the end of 1982. Getzen attributes the formulation of cost control legislation and the apparent impact, or lack of impact, of the legislation on macroeconomics (30). Inflation, recessions, and deficits favor the implementation of legislation to control costs, and the lagged effect commonly associated with a recession may be sufficient to make such controls appear successful. Legislation serves to equilibrate health care spending with national income and would probably be unsuccessful under different macroeconomic conditions. Getzen views DRGs as a delayed legislative response to the 1980 and 1982 recessions, and the resulting decreases in gross national product caused a reduction in health care spending in 1984 and 1985, not the implementation of DRGs. The record number of hospital closures in 1988 has also been attributed to DRGs, but the largest number of closures occurred in Texas, which was devastated by a catastrophic local recession when the price of oil dropped precipitously. Getzen predicts that macroeconomic forces, not future relative value scales, ambulatory visit groupings, or other types of physician DRGs, will determine the future economic direction of the health care system.

Prospective reimbursement has posed a challenge for clinical laboratory scientists, including clinical microbiologists. The DRG system of reimbursement has converted hospital laboratories from profit centers to cost centers funded by hospital income, at least for inpatient laboratory testing (6, 7, 62, 70). Hospital Medicare inpatient operating income has become predetermined on the basis of DRGs and is independent of laboratory test volume and complexity. The laboratory must compete with other services for its operating budget (61, 70). Hospital administrators have reduced laboratory operating expenses by constraining laboratory growth and development (7, 61, 70). Reductions in personnel, supply, and capital budgets have contributed to overworked personnel and created quality and productivity problems (9). More than 70% of laboratories have undergone budget reductions (61). In actuality, the advent of prospective payment has created an economic paradox for the clinical laboratory. In order to minimize the length of stay and decrease total patient cost to the

hospital, work load has increased in some laboratories without a commensurate increase in reimbursable laboratory income or operating budget, although review programs implemented to contain costs in the DRG era have reduced some test ordering on hospital inpatients (24, 37, 59, 61). Because clinical microbiology laboratories are less automated than chemistry or hematology laboratories and both specimen volumes and complexity continue to increase, clinical microbiology may be more adversely affected by prospective payment than the other laboratory areas (7). In addition, physician malpractice concerns, physician turnaround time demands, enhanced availability of laboratory tests, and the aging population have contributed to increased laboratory operational costs (61). Prospective payment programs have not adjusted their fee schedules to accommodate rising laboratory costs.

Laboratories have responded to the fiscal restraints imposed by PPS by attempting to reduce operational costs without adversely impacting quality (6, 59). Laboratory testing has shifted from the hospital laboratory to the outpatient laboratory, where separate reimbursement is allowable, including preadmission testing, which has increased (6, 59). This shift of testing and revenues to the outpatient laboratory may limit future capital funds for hospital laboratories, and in Canada, this mechanism to control total health care costs has had an especially restrictive effect on laboratories (37). Laboratories have begun to address the essential issues of test utilization and unit costs to optimize the fiscal management of all patients, not just DRG inpatients (6, 25, 62). The cost-effective utilization of clinical laboratory tests requires an assessment of whether or not a particular test has sufficient diagnostic value for a given diagnosis and the establishment of criteria to limit the extent of specimen processing to that which is most likely to be clinically relevant. The elimination of unnecessary, inappropriate testing will also reduce the production of clinically misleading information and information overload, thereby improving the quality of care concomitant with cost reduction. However, hospitals have often elected to avoid the discussion of what constitutes appropriate test utilization. The implementation of utilization controls requires education, effective communication, and a close working relationship with clinical services. Although computers can track individual physician ancillary service usage by specific DRG and detect outliers, physicians continue to have little incentive to reduce utilization and, thereby, hospital costs.

Rationing and Prioritization of Health Care Resources

In the past, society was willing to expend infinite dollars on individual patient health care, but today society has determined that health care resources must conform to the economic reality of society's ability to pay for such services (1, 5, 54, 55, 67). Therefore, it must be decided what resources are available for health care and how and to whom they will be distributed. Economic constraints require that a compromise be reached between individual welfare and limited societal resources. The objective is to identify how best to spend society's resources such that the health of the most people is improved. The concept of rationing is anathema to many people, although health care has always been rationed since no society has ever been able to provide all the care its people might want to use (44, 54). For example, patients are excluded from the existing health care system by several mechanisms, including lack of geographic access to a medical facility, inability to pay, and already limited resources (54). However, because third-party payers reimburse the vast majority of health care costs, patients have come to expect and demand medical services (44). This has resulted in the individual's claim to resources reigning supreme over the good of the whole. Identifying a middle ground between what is best for the individual and what is best for society will be difficult, but it is essential that choices be made if resources are to be limited (55, 67). Resources will have to be distributed among preventive, acute, and chronic care, with inevitable reductions in the current level of acute care (55). Health care rationing requires knowledge of the cost benefit of the various services including the assessment of outcomes (54). Although important for the establishment of health care priorities, there are limits to cost-benefit data, and value judgments may be necessary (67). Several states have begun to address the issue of establishing health care priorities that can be used to define adequate, not optimal, health care (67). State residents have been involved in defining local needs in the context of the federal and state budgets. Benefits will be covered in a predetermined order of priority until the budgeted resources are depleted, thereby yielding a functional definition of adequate health care. In 1987, Oregon chose to expand Medicaid to provide health care for all of its low-income residents (67). Oregon decided that the number of insured people was more important than the number of services provided, which means that the covered benefits for the entire population will vary depending on the availability of state revenues. Whether one calls it rationing or prioritization, what has been proposed in Oregon will occur nationally if a national health insurance program is legislated since any universal-access health care program must determine the scope of coverage, thereby requiring the establishment of priorities and an operational definition of adequate health care (67).

Not surprisingly, some physicians are adamantly opposed to health care rationing (1, 63). Arguments against rationing range from dire predictions of adverse patient care impact to the need to exhaust alternative cost containment strategies. Angell contends that much of the medical care in the United States is unnecessary and that if unnecessary care were reduced sufficient resources would be available for beneficial care, even expensive care (1). Therefore, rationing to control costs and to limit availability of beneficial services is premature and would be needless once the existing waste in the system is eliminated. Angell targets the following three categories as representing unnecessary medical care: "little ticket" ancillary services performed without valid indications, including laboratory tests; "big ticket" expensive procedures and operations performed in circumstances of dubious value; and aggressive treatment of terminally ill patients (1). Although cost containment directed at misutilization and overutilization of existing services could undoubtedly conserve substantial health care resources, to date, an effective cost control mechanism has yet to be identified and successfully implemented on a grand enough scale to significantly impact health care expenditures.

Educational Strategies

A number of educational strategies have been developed to reduce inappropriate use of ancillary services. Some approaches have been successful, and others have proved to be relatively ineffective. The following strategies have been proposed to attempt to modify physician test utilization: formal didactic instruction in the use of laboratory information (15, 35, 50), dissemination of cost information for routine procedures and laboratory tests (35, 48, 50, 63, 73), written guidelines or protocols (73), audits of laboratory usage (35, 38, 63, 72), personal incentives (73), and feedback systems (3, 29, 38,

50, 72, 73). Mixed results have been reported with virtually all of the methods used to control test utilization. Successful efforts to reduce the misuse of laboratory resources have included a long-term commitment to cost containment, a combination of educational programs, and active intervention to reinforce educational efforts (50, 72, 73). Physician education alone is not an effective mechanism to consistently contain costs. According to educational psychology, a teaching stimulus has to be repeated if a learning effect is to persist; if not, the effect is transient (73). In addition, a pervasive positive institutional and physician attitude towards cost containment and related activities is crucial for the sustained success of any of these methods (3, 29, 50, 73). Appropriate attitudes can be developed if the rationale for reducing unnecessary ancillary test use is clearly stated (50, 73). However, the concept of cost containment cannot be used as the sole reason for a cost containment program. Instead, it is important to emphasize the improvement in the quality of care that will occur as a result of reducing overutilization, underutilization, and misutilization of laboratory tests (50, 73).

A variety of approaches have been used to educate both house staff and attending staff physicians regarding appropriate laboratory test utilization and the financial impact of their actions (35, 50, 73). Methods have included lectures, seminars, guidelines in the form of decision support systems, test information manuals, cost containment newsletters, manuals listing test charges, and staff meetings. Topics covered include sensitivity and specificity of particular tests, the interpretation of test results based on probability theory, iatrogenic risks, clinical decision making, cost containment programs, and health economics, including reimbursement mechanisms (35, 73). The premise is that if physicians know how to proceed in a given situation, unnecessary tests will be reduced and expensive testing will be minimized. Modern information technology has made it possible to merge individual patient medical record data with criteria for action, thereby generating a list of alternative selections for how to proceed with a particular patient (73). These decision support systems have reportedly successfully reduced unnecessary testing but require tremendous technical and medical support. Efforts to make physicians aware of actual test cost have had a marginal effect on test ordering patterns (73). Interestingly, although one-third of physicians in training admitted to actively discussing the cost of laboratory tests within the past week, 50% of the tests were ordered without concern for cost, leading to the conclusion that cost awareness has little impact on test ordering practices (73). Similarly, staff meetings, written guidelines, and lectures without active intervention have failed to have a sustained effect on the level of test requests.

Feedback systems are based on the premise that, although physicians have knowledge about appropriate test utilization, information on their own performance in comparison to their peer group helps them to adhere to utilization policies (73). Success is predicated on the information being specific for a physician, including clear identification of his or her precise position relative to his or her peers, since individuals prefer to act in concert with their peer group and not deviate from the mean. Physicians need to be made aware of the expected norms. The information must also be provided in a timely fashion, usually data collected within the past 4 weeks (73). Just one ranking report can yield an immediate, marked reduction in laboratory test work load and expenditure. Types of feedback include information on test request patterns and utilization, information on the cost of investigations generated by a physician, physician ranking positions based on the numbers of tests ordered or test costs, and medical chart review (35, 50, 73). The feedback of clinical chemistry laboratory data to general physicians was reported to lead to an immediate and sustained reduction in test requests and expenditure, presumably because comparative feedback provides a continuous reminder of behavior and a stimulus for behavior modification (29). The changes persisted after the feedback was stopped. These data suggest that laboratory data feedback is effective in both achieving and maintaining modified physician test ordering behavior. Although physicians were not given hematology data as part of the feedback intervention study, hematology test requests were also reduced, and this suggests that the feedback had modified physician ordering patterns towards general laboratory testing. Another study monitored the effect of monthly comparisons of physician work load statistics in conjunction with educational information and guidelines for hematology test utilization (3). This combined approach caused a sustained test reduction of 20%, with the greatest impact observed on the junior internal medicine staff members who had the least experience and were the most excessive users of the service. When physicians were ranked in order of increasing laboratory costs, 29% of laboratory costs were reduced (73). However, when excessive numbers of serum calcium and lactate dehydrogenase tests were reviewed and the requesting physician was informed, test ordering patterns remained unchanged (73). This project was probably unsuccessful because it lacked comparative peer ranking information. Another feedback technique that can achieve test utilization reductions is chart review (38, 50, 72, 73). This can be especially effective with house staff when the review is performed by a senior staff member (73). Test request reductions have ranged from minimal changes to a 47% decrease following patient record review; however, the effect appears to be transient (50, 73). Chart review combines feedback with education, including individualized attention by a senior staff member. Finally, the Massachusetts Ancillary Services Review Program has been used to identify significant inappropriate ancillary service utilization, to educate physicians and hospitals, and to stimulate corrective action plans (38). Specific corrective action plans have ranged from the formulation of utilization committees to the review of all standing orders to the development of specific criteria for requesting a particular culture. The Ancillary Services Review Program is based on the expectation that audit and feedback strategies effectively modify physician behavior.

Reference and Centralized Laboratory Services

To conserve ever dwindling resources, many hospital laboratories have elected to use reference and centralized laboratories more extensively since the implementation of prospective payment. Hospital laboratories have experimented with cluster laboratories, shared services, various contract management relationships, and transfer of all but routine or emergency services to an external laboratory (59). Whereas hospital laboratories have experienced new clinical and financial demands in the DRG era, hospital-independent commercial laboratories continue to operate in an environment with a lower overhead as a result of handling specimens primarily from a relatively healthy, nonhospitalized population. Because of the usual lack of urgency associated with nonhospital laboratory testing, the following increased efficiencies can be realized: test batching, infrequent panic value reporting, and minimal consultations (59). However, many hospital laboratories have been managed cost effectively. Shaw and Miller propose that the high prices associated with hospital laboratory

testing are not the result of inefficient hospital laboratory operational practices but the result of the hospital management convention to assign the costs of non-revenue-producing hospital services to laboratory test prices (59). If overhead expenses and related charges were assigned to the cost centers where they belong, hospital laboratory test charges would be reduced dramatically.

A number of arguments have been cited in support of reference and centralized laboratory facilities (12, 59). Some centralization of laboratory services is essential for efficient, accurate performance of low-volume, specialized testing, and this centralization is beneficial even for comprehensive hospital laboratories. In smaller hospital laboratories, some routine testing may be performed more cost effectively in alternative testing sites, and the extent of on-site service may be reduced. Reference laboratories can be especially useful when a new test is initially made available, and the eventual clinical utility of the test is unknown. This can alleviate the premature investment in capital equipment or new personnel that may prove to be unnecessary. Others argue that centralized laboratories allow both routine and sophisticated tests on outpatients and inpatients to be performed in a more cost-efficient and quality-controlled environment and that this centralization will be facilitated by the reduction in health care dollars and the resulting elimination of duplicate health care facilities and services (12). It has been stated that, ultimately, only a centralized laboratory with sufficient work load and multiple markets will be able to provide and afford the necessary specialized technical personnel, level of quality control, automated equipment, and volume discount buying needed to maintain and improve test accuracy and variety. It has been reported that a supply budget can be reduced more than 20% as a result of volume discounts received by a large centralized laboratory (12). It has been suggested that such centralized laboratories provide greater professional satisfaction and opportunities than is found in smaller institutions (12). The counterargument to the objection that unacceptable delays are inherent in a centralized laboratory system is that, because of higher volumes, tests are more frequently performed in a centralized laboratory, leading to decreased turnaround times and reduced hospital length of stay (12). Even if a specimen must be transported many miles, routine tests can be performed within 24 to 48 h following specimen collection and the results can be transmitted immediately to the physician or hospital via computer, telephone, or fax machine. Except for certain labile specimens or stat procedures necessary for immediate patient management, a reference or centralized laboratory can offer increased accuracy and test availability at a lower unit cost (12).

In spite of multiple reports documenting significant cost savings in reference or centralized laboratory settings, some experts have cited concerns about such laboratories, especially in a prospective payment environment (12, 49, 58, 59, 61). Furthermore, there is some question as to whether or not commercial reference laboratory testing is truly less costly than testing in a well-managed, cost-conscious hospital laboratory. Both types of laboratories have direct test costs that are similar, and each accrues costs that are unique to its setting (59). Hospital laboratories incur additional costs as a result of off-shift emergency needs, and reference laboratories have the additional costs of marketing, off-site transportation, and remote reporting expenses. When discounted, reference laboratory test charges are compared with the direct test costs in a comprehensive, sophisticated hospital laboratory, it is virtually always less expensive to perform the test in-house than to send it to a reference laboratory (59). It is important to realize that, even if tests are sent to a reference laboratory, the hospital laboratory remains responsible for many of the preanalytic and postanalytic phases of testing essential for optimal care and their associated costs (59). If a test result is critical to patient care and turnaround time must be kept to a minimum, a hospital laboratory may be required to establish the test even if it is at a financial loss (59). Furthermore, it is argued that patient care is significantly enhanced by on-site testing (12, 58, 59, 61). Turnaround times, and therefore length of stay, can be reduced when testing is performed in the hospital laboratory (12, 61). On-site testing provides essential support to the critically ill patient in a timely fashion, thereby reducing morbidity and associated costs (12, 61). There are concerns about the adverse impact of extended transportation on the quality of cultures for microorganisms (12). It is also thought that the presence of the laboratory staff on site improves specimen collection, test ordering, and communication with nursing and medical staff (12). Aside from patient care concerns, financial and management problems can arise from reference or centralized laboratory testing. Community hospitals rarely have sufficient stat testing needs to support the laboratory structure that is essential to ensure accurate critical value results. Alternatively, if an adequate support structure is available, the laboratory also has the capability to perform the majority of routine testing with minimal additional costs since contracting out laboratory tests reduces only the variable direct costs (12, 59). Referral of tests also means that the hospital loses profits that may be associated with the testing. In addition, as laboratory testing volume declines, the efficiency associated with high-volume testing is gradually diminished to the point at which either more testing must be sent to reference laboratories or ideas to expand in-house test volumes must be entertained. Hospital laboratory testing can be expanded by joint ventures with other hospital or private laboratories, by performing some or all of reference laboratory testing in-house, or by developing intensive outreach programs to compete for outpatient testing in a variety of settings (59).

General Laboratory

Clinical laboratories have developed diverse strategies to respond to changes in funding and work load. This response has been necessary, because diagnostic tests have been viewed as frequently unnecessary and as a large component of total health care expenditures (64). Public pressure and changing health care needs have precipitated both subtle and radical laboratory changes to more effectively use allocated resources. The DRG PPS has provided tremendous incentive for hospital laboratories to reduce costs even as the complexity and number of tests per patient have increased in some institutions. However, increasingly common is a progressive decrease in test volume as a result of prepaid health plans and utilization controls (58). Since the average hospital laboratory can accommodate at least 25% more tests with existing personnel and equipment, many laboratories have elected to increase operating efficiency by acquiring additional test volume through marketing their services (58). Policies that improve the quality and usefulness of the test information by actually doing less have been developed (4). Winkelman has organized the strategies for laboratory cost containment into the following categories: straight cost cutting, internal operation modifications, service degradation, utilization reduction, shared hospital services, and reorganization (69).

The most conventional approach to cost reduction is simple straight cost cutting of the operational budget, providing such

opportunities still exist (59, 62, 69, 70). This strategy has been described as being "transparent" to the laboratory client since all laboratory functions, including teaching and research, continue unabated at the same frequency and quality (69, 70). No attempt is made to alter physician test ordering behavior or availability of laboratory services. The focus is on supplies, other direct expenses, and personnel expenses to reduce costs (59, 62, 69). Supply costs, which represent approximately 9 to 20% of all direct costs, have been curtailed by group purchasing, improved inventory control, persuasive negotiation with vendors, and volume discounts (59, 69). Personnel expenses have been minimized by hiring lower-qualified personnel at a reduced salary and purchasing automation that reduces the labor component of testing (59, 62, 69). These measures can reduce direct expenses by a maximum of 20% (69). However, unit costs remain relatively expensive because of the unchanged fixed costs (62). Therefore, other methods must be implemented to further contain costs.

Modification of internal operations can also achieve cost containment through changes that are invisible or transparent to the user (20, 59, 62, 69, 70). The following opportunities to conserve costs can be explored by each clinical laboratory: increase automation, introduce computerization, reduce the number of workstations, employ management practices that improve productivity, review policies and procedures to improve productivity, use cost accounting to assist in the selection of test methods, distribute work load evenly throughout the work force, reduce duplicate testing, reduce excess quality control or quality assurance activities, reduce unnecessary proficiency testing, make reagents in-house, reuse disposable plastic and glass supplies, stagger work hours, reduce support services in the laboratory, and use the lowest-level qualified employee to perform a specific task (16, 46, 59, 62, 69, 70). These internal operational changes can reduce direct costs with little or no adverse impact on service. The cost savings realized vary considerably depending on the institution, although general laboratory direct-expense reductions of approximately 7% and microbiology laboratory reductions of about 11% have been reported in the literature (69).

Degradation of services and functions is apparent to the clinician user and has been described as being "translucent" rather than "transparent" as with the previously described strategies (69, 70). Physicians continue to order tests unimpeded by utilization controls. However, the response level of the laboratory will be perceived as being diminished. Clinical service, development, education, and research can be selectively degraded with the objective to maximize cost benefit and minimize adverse impact on quality of care. Opportunities to degrade clinical service activities include the following: reduce testing frequency to achieve the economy of scale associated with larger batch sizes, reduce evening and night shift services, reduce stat testing, and reduce the extent of services available on site (16, 69, 70). The impact of these service reductions on patient length of stay needs to be determined to ensure that the laboratory budget savings do not cause a disproportionate increase in total hospital costs. However, there is controversy as to what extent a quick test turnaround time will reduce the length of a patient's hospital stay. Some individuals believe that each minute reduced from the turnaround time translates to a decreased length of stay. Others profess that clinical laboratory values rarely impact on a patient's discharge and, therefore, the cost associated with many rapid results may be difficult to justify (47). The following nonservice functions of the laboratory can be reduced or eliminated: new test development, test method modifications, equipment upgrades, teaching activities, and research (69, 70). The cost savings associated with service and function reductions is unknown and depends on the magnitude of degradation implemented (69).

Efforts to contain laboratory costs by controlling test utilization have been diverse, with variable outcomes reported. Since overutilization of ancillary services has been reported to be a major contributor to escalating health care costs, it is not surprising that laboratory testing has been targeted for stricter control. The General Accounting Office reported that about 7% of hospital laboratory testing was unnecessary (69), and other studies have demonstrated that only 5% of laboratory test results actually influence patient management (73). In 1975, an ad hoc committee in Connecticut and, in 1977, a meeting of the College of American Pathologists recommended that institutions establish controls on laboratory utilization to minimize misuse of laboratory services (23). Reduction of laboratory costs by improving test utilization also has the potential to maintain and even enhance the quality of patient care (71, 73). Concern about unnecessary microbiologic testing, some of doubtful clinical relevance, has been noted in the literature (4). The lack of automation in microbiology, and therefore the absence of associated productivity benefits, has also increased interest in improving the utilization of microbiologic data (66). The critical question that needs to be answered is whether or not a test result impacts on patient management (73). Optimal testing strategies can be developed through a dialogue between laboratory professionals and the affected clinical service(s), including discussion of the medical, scientific, and economic aspects of the decision process (61). Communication is essential to maintain an environment that is conducive to quality improvement and cost containment. Then testing can be restricted to high-quality samples that will improve the clinical value of the information. However, as Winkleman indicates, utilization controls interfere with a physician's ordering behavior and are a cost reduction effort that is quite apparent to the user, thereby earning the designation of an "opaque" strategy (69, 70). A variety of approaches have been employed to reduce test utilization, including the following: education, problem-oriented test requisition form redesign, financial incentives, testing algorithms, comprehensive practice protocols with a decision tree, consultation with laboratory staff prior to test performance under defined conditions, fixed admission testing panels, test rationing, and copayment (15, 23, 62, 69). When a limit of eight tests per patient day was established at one hospital, the daily work load of the laboratory decreased 25%, and the average number of tests per patient day declined from six to two (73). In health maintenance organizations, where financial disincentives for overutilization exist, costs are 10 to 40% less than that found in fee-for-service practice (50). The cost reductions associated with the elimination of unnecessary testing has been reported to range from minimal to substantial savings (26, 56, 62, 69). It is important to note that the reduction in costs is not proportional to the reduction in test utilization, because the fixed laboratory costs are not dependent on the volume of testing performed (26, 69). Finkelstein estimates that a hypothetical 20% decrease in chemistry test utilization would reduce laboratory costs a maximum of 12.5%, although the laboratory administrative staff predicted a savings of substantially less (26). Another report determined that a 10% reduction in utilization of a high-volume test resulted in an actual cost savings of only 1.3% of total costs and 1.8% of direct costs, whereas a 10% reduction in utilization of all tests yielded a 4.0% total cost reduction and a 5.2% direct cost reduction (69).

A laboratory may elect to reduce costs by sharing laboratory

services with other hospitals or commercial laboratories (57–59, 62, 69, 70). Physician users may view a merger or joint venture as providing either an increase or decrease in function depending on how the services of the collaborative effort compare with the former services (70). The main objective of shared laboratory services is to attain maximum service at minimum cost by combining the positive attributes of a hospital laboratory with those of a reference laboratory (57). Hospital laboratories provide service and quality at an extremely high fixed cost per test, and reference or commercial laboratories achieve lower costs with economical batch testing at a loss of turnaround time and individualized service (57). A post-Tax Equity and Financial Responsibility Act laboratory model, referred to as a cluster laboratory, that would combine the benefits of high-volume work load with high-quality service (57, 58) has been proposed. Depending on the population size and density, a cluster laboratory would serve 6 to 15 hospitals in a region or a combined service base of 3,000 beds in order to obtain sufficient volume to perform tests at the lowest unit cost possible (57, 58). In this model, stat tests, representing approximately 30% of the work load, are performed in each participating hospital, and the conveniently located central laboratory receives and batch tests 60% of the work (57). The remainder of the work, representing esoteric tests, is sent to a reference laboratory. Whether a cluster laboratory model or another shared service is developed, the objectives are to accommodate increased nonhospital patient work load and to eliminate expensive duplicate facilities, instrumentation, personnel, and support services (62, 69). Cost savings of approximately 9% as a result of shared hospital services have been reported (69).

Finally, a reorganization strategy that alters the existing organizational and fiscal relationship between the laboratory and the hospital may be implemented (69, 70). Again, laboratory clients may discern either positive or negative service impact depending on how services in the new organization compare with the performance of the previous entity (70). Types of reorganization include institutions specializing in specific types of medical services, hospital services sharing work load and resources, hospital outreach to the community, institutions "going public," and institutions "going private" (70). Reorganization strategies may be pursued to achieve the following objectives: reduced unit costs as a result of increased work load, increased nonhospital patient work load, fee schedule flexibility and reimbursements available to for-profit entities, a separate hospital entity to compete with commercial laboratory operations, and sale of the laboratory to a professional or commercial corporation to enhance management quality (69). The savings achievable through reorganization are unknown, and Winkleman concludes that the existence of true cost savings associated with new off-site corporate entities remains to be proven since the most inefficient and expensive laboratory services must continue to be provided 24 h a day at the hospital (69).

CONCLUSIONS

Health care spending has continued to grow with respect to the rest of the economy. The costs of clinical laboratory services are considered to be an important contributor to the general inflation in medical and health care costs during the past 20 years, resulting in a heightened concern with regulating clinical laboratories and controlling unnecessary costs associated with laboratory testing. Whether one ascribes the excesses to bureaucratic systems, waste and inefficiency on the part of health care workers, industrialization and commercialization of medical care, new technology, public expectations and overconsumption, open-ended third-party payments, or physician compulsiveness and insecurity, the cost of health care has exceeded what the public is willing to pay for, especially in view of the growing realization or perception that increased resource commitments have only marginally improved the gross indicators of health. Although many factors contribute to and compound the escalating health care cost problem, the increased utilization of health services, particularly diagnostic services, is considered to be one of the most important elements. Responsibility for excessive laboratory use can be assigned primarily to the following four groups: practicing physicians, physicians in training, patients, and the clinical laboratory. Although the increasingly wasteful use of laboratory resources has contributed to the escalating cost of health care without concomitant benefits, increased laboratory testing also has had serious adverse consequences on several noneconomic aspects of health care, including iatrogenic complications and production of excessive information that can obscure crucial information. Therefore, excessive information can be a liability to patient care rather than an asset, and less testing can be more beneficial. Technology not only has altered the ability of medicine to diagnose and treat disease but also has changed the public's expectations of health care. Divergent opinions regarding the economics of laboratory technology exist. Selective implementation of technology, in conjunction with barriers to limit access to a new test, has the potential to save health care dollars by increasing productivity. It is essential to determine the clinical usefulness of the information yielded by a new method. Ideally, any cost containment measure should maximize benefits and minimize harms. The strategies to contain escalating health care costs have ranged from individualized physician education programs to government intervention. Laboratories have responded to the fiscal restraints imposed by prospective payment systems by attempting to reduce operational costs without adversely impacting quality. Although cost containment directed at misutilization and overutilization of existing services has conserved resources, to date, an effective cost control mechanism has yet to be identified and successfully implemented on a grand enough scale to significantly impact health care expenditures in the United States.

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