Measuring Outcomes: Why Now?

David L. Witte

Intense scrutiny of the American healthcare paradigm will alter the activities of patients, providers, and payors. Government reform and marketplace-driven managed care programs create uncertainty. Quality, access, and cost concerns also drive change. Quality is conformity to requirements, and specification of requirements creates policy debate. Variability in utilization creates an accountability chasm between payors and providers that cannot be bridged without understanding the uncertainties in "appropriateness" research. Quality and access appear secondary to cost. Cost discussions must differentiate cost and charge. Inappropriate charge benefit analyses may temporarily benefit a specific organization but are unlikely to create long-term societal benefit. Multiple transitions have begun, including a shift from disease care to healthcare, provider mentality to consumer mentality, and provider autonomy to collaboration and accountability. Laboratories will be expected to provide outcomes, not tests; income will be related to covered lives, not volume, and profit will shift from "piecework and efficiency profit" to "prevention profit." Only good "outcomes" measurement can reduce uncertainty. The laboratory contribution to value in care processes remains unclear. What information is added by each result? How can results help prevent the need for future services? These are our challenges.

Indexing Terms: outcomes/prevention/health policy/gentamicin/thyrrotropin/sepsis

The media reports that American medical care is high quality but too costly and not available to all. The successes in quality and the failures in costs are both attributed to dramatic technologic advances. The costs are also attributed to rising public demands for care. The political will to adopt sweeping legislation has waxed and waned. However, there is a broad-based, business-initiated stimulus to develop a more rational healthcare delivery system. These concerns about quality, cost, and delivery system sound like contemporary 1994 debates. However, they were presented in 1970 (1).

Scrutiny of healthcare delivery is intensifying. Multiple powerful public desires drive actions by government agencies and marketplace participants. These actions are creating transitions in the American healthcare environment. Many of the transitions signal an increased expectation for accountability by providers and payors for quality and cost. Improved outcome information is needed to meet this expectation of accountability.

Quality, Access, Cost, and Uncertainty

Eddy (2) indicates quality, access, and cost are the three factors driving American healthcare reform. Most importantly, the excessive rate of increase in healthcare spending drives both government and the marketplace to consider sweeping changes in healthcare delivery. Changing the financing system alone is unlikely to address this "excess inflation." The Congressional Research Office attributes medical price increases as follows: 42% to general price inflation, 9% to population growth and aging, 17% to excess medical inflation, and 32% to increased volume and intensity. The excess inflation and increased service volume represent the healthcare sector's opportunity to address price increases. Success requires that these efforts be accompanied by thoughtful evaluation of both medical evidence and cost-accounting procedures. The autonomy of decision makers will be replaced by collaborative processes involving all three stakeholders: patients, payors, and providers (the three Ps).

I believe uncertainty is the fourth and most significant driving force for healthcare change. If unequivocal information could substantiate health benefits, costs, and risks for each intervention, then society could probably make rational policy. Most markets are controlled through interplay of supply, demand, and consumer sovereignty. But most healthcare consumers lack sufficient information for sovereignty, and expect a physician to help make decisions (3). Consumers assume physicians know the effectiveness of tests and therapies and what the consumer needs. Consumers also expect that the physician will act to maximize consumer benefits at the most efficient cost. Wennberg et al. (3) suggest that physician uncertainty regarding outcomes, cost, and consumer expectations precludes effective satisfaction of the consumer's expectations. This situation will be rectified only by improving healthcare outcome information and sharing it with the decision makers.

The focus on outcomes information assumes the care delivered was appropriate or necessary for the well-being of the consumer. What physical and historical findings indicate intervention is appropriate or necessary? Rand Corporation has studied indicators for appropriateness and necessity of care. Expert panels agree on only 40% of all indications of appropriateness for coronary angiography and agree that only 29% of appropriate indications are necessary or crucial (i.e.,

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inappropriate to omit and expected to yield large benefits) (4). Appropriateness measurements in geographical areas of high and low utilization show similar "inappropriate use," suggesting that inappropriate use is not the driving force for higher utilization (5). How can care decisions be made more certain if we lack outcome information?

Methods to judge quality and appropriateness are relatively new and have uncertain sensitivity for detecting poor quality and inappropriateness, as well as unknown specificity for identifying good quality and appropriateness (6). Care can be falsely labeled inappropriate or falsely labeled inappropriate. Under many circumstances, the rate of inappropriateness may be overestimated. Results based on expert panels often only solidify old beliefs rather than lead to new information. Our abilities to reproducibly measure the quality of care need significant improvement (7, 8).

Consumers have assumed physicians know what to do, but uncertainty challenges that assumption (9). The geographical variations in practice, estimates of inappropriate care, variable provider perception of care outcomes, and identification of poor evidence have shaken the assumption of knowledge that supports provider autonomy in care decisions. Care decisions are complex. Oversimplification, qualitative thinking, and hoping for potential benefit contribute to faulty decision making. To rebuild confidence in the healthcare delivery system, we must insist on quantitative information about actual benefits (9). This means collecting outcome data.

Government and Marketplace Responses

Early 1994 brought attention to managed competition as a purchasing strategy to maximize public value in healthcare delivery (10). The competition was to be based on rational microeconomics by using measured outcomes in units of dollars, quality, and satisfaction. The successful providers would be rewarded with more customers. The sponsoring payors would be able to pool more customers and distribute risks.

Businesses suggest that incentives in healthcare are sufficiently skewed to render managed competition ineffective (11). Teisberg et al. (11) suggest: (a) payors are frequently adversarial with patients and providers; (b) patients frequently lack cost sensitivity; (c) patients are fragmented and lack power; (d) provider incentive to increase total costs leads to increases in volume and local duplication of facilities; (e) substandard providers and payors are overprotected from failure; and finally (f) patients, payors, and providers all lack quantitative quality and outcome information. Teisberg et al. (11) further suggest that competition can preserve existing quality and deliver better value if innovation is encouraged and incentives realigned. This will be successful if the patients, payors, and providers have quantitative outcome information to support good decision making.

The National Association of Manufacturers published "Buying Value in Health Care" (phone 800-637-3005 for reprints), which focuses on managed care expectations to adopt the continuous quality improvement model, track healthcare outcomes, and adopt care guidelines. Proponents point toward dollar savings for business. Opponents cite risks for undertreatment and discrimination against the sicker patients (12).

The rising frequency of ruptured appendices among participants in managed care programs (13) has caused some to wonder whether care quality is safe under managed care. A 1994 report from nearly 100,000 cases showed an association between frequency of complicated (ruptured) appendicitis and type of insurance coverage (14). These findings suggest barriers to care that should be considered in any healthcare policy decision. Risks must be recognized and incentives must be carefully designed if managed care is to yield good societal outcomes in addition to benefits for a specific subgroup.

The proponents of managed competition suggest that managed care has failed to contain costs (15). Medical inflation has not slowed, but optimism seems justified that 1994 medical inflation will be less. The lack of quantitative comparative quality and outcome information is one reason why managed care may not be containing costs as hoped (15).

Transitions

Marketplace government responses to uncertainty and to the desires for quality, access, and reduced cost are creating many transitions in the healthcare environment (see Table 1).

**Process orientation.** Laboratory medicine must be seen as a part of the total process of care. Analysis must be viewed as part of the process of laboratory medicine care. We must maintain expertise in the activities on the perimeter of Fig. 1 while increasing our ability to focus those activities on the final outcomes.

**Outcome orientation.** Health outcomes are complex. We have an explosion of data (16), but we need increas-

Table 1. Transitions in healthcare provision.

<table>
<thead>
<tr>
<th>Task orientation</th>
<th>Process orientation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turf-protective</td>
<td>Population-protective</td>
</tr>
<tr>
<td>Provide services</td>
<td>Provide outcomes</td>
</tr>
<tr>
<td>Provider orientation</td>
<td>Consumer orientation</td>
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<tr>
<td>Provider autonomy</td>
<td>Collaboration and accountability</td>
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<tr>
<td>Variable certainty</td>
<td>Agreed-upon certainty</td>
</tr>
<tr>
<td>Judgment-based</td>
<td>Evidence-based practices</td>
</tr>
<tr>
<td>Disease care</td>
<td>Health care (prevention)</td>
</tr>
<tr>
<td>Placework profit</td>
<td>Prevention profit</td>
</tr>
<tr>
<td>Volume</td>
<td>Prevented need for care</td>
</tr>
<tr>
<td>Occupancy</td>
<td>Vacancy</td>
</tr>
<tr>
<td>$ for service</td>
<td>$ for covered life</td>
</tr>
<tr>
<td>Fully allocated accounting</td>
<td>Known cost of production</td>
</tr>
<tr>
<td>Compete on price</td>
<td>Compete on value (benefits/cost)</td>
</tr>
<tr>
<td>Centralization of service</td>
<td>Dispersal of service</td>
</tr>
<tr>
<td>Economies of scale</td>
<td>Economies of simplicity</td>
</tr>
<tr>
<td>Mass-produced benefit</td>
<td>Individually chosen benefit</td>
</tr>
<tr>
<td>Corporation</td>
<td>Cottage</td>
</tr>
</tbody>
</table>
ing integration of the data to obtain information, knowledge, and wisdom (17). Outcome data relate to patients' satisfaction, functional status, and health status. Many instruments are available to study general health, as well as health and functional status in specific conditions (18, 19). Laboratorians need to assess the contribution of laboratory care to these general measures as well as to study the impact on more specific outcomes.

Two coworkers and I recently studied the effectiveness of a gentamicin dosing and monitoring protocol built on collaboration among physicians, nurses, pharmacists, and laboratorians (20). We hypothesized that local data would confirm literature data and indicate that higher gentamicin peaks were associated with higher survival rates from gram-negative bacteremia.

The protocol encouraged physicians to order gentamicin doses of 2 mg/kg body wt., which was expected to yield peak concentrations near 8 mg/L, if the patient's volume of distribution was near the average of 0.25 L/kg. The first dose was monitored, and patient-specific pharmacokinetic data were used to guide future doses and intervals to maintain peak concentrations of 8 ± 2 mg/L, with trough concentrations near 1 mg/L. Monitoring was repeated on alternate days to assure appropriate concentrations.

Consecutive patients with blood culture-positive, gram-negative bacteremia were studied retrospectively. Table 2 shows that higher initial aminoglycoside peak concentration is nearly monotonically associated with higher survival frequencies. Review of results from the 36 more severely ill patients (with classified severity of 3 or 4 by the MEDIGROUPS system) (21) showed that if the initial and average gentamicin peak concentrations were >6 mg/L, 18 of 20 (90%) survived; if these concentrations were not achieved, only 8 of 16 (50%) survived. We concluded that our program confirmed literature data, and higher peak concentrations improved outcomes. Laboratorians need to focus attention on outcomes (Fig. 1).

**Consumer orientation.** The provider mentality is characterized by the "I know what is best for you" attitude. Both payors and patients have become aware of provider uncertainty and now doubt the provider attitude. More importantly, it is the perceptions of the patients and payors that will ultimately determine what is done. Individuals value the risks and benefits of specific healthcare interventions differently (22), and the quality of life is a uniquely personal perception (23). It may be essential for one individual to play tennis, whereas another is satisfied by less vigorous

### Table 2. Initial aminoglycoside peaks.

<table>
<thead>
<tr>
<th>Peak, μg/L</th>
<th>Total</th>
<th>Lived</th>
<th>Died</th>
<th>Proportion who lived</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonea</td>
<td>25</td>
<td>17</td>
<td>9</td>
<td>0.65</td>
</tr>
<tr>
<td>&lt;5</td>
<td>14</td>
<td>11</td>
<td>3</td>
<td>0.79</td>
</tr>
<tr>
<td>5.0-5.9</td>
<td>12</td>
<td>9</td>
<td>3</td>
<td>0.75</td>
</tr>
<tr>
<td>6.0-6.9</td>
<td>16</td>
<td>14</td>
<td>2</td>
<td>0.87</td>
</tr>
<tr>
<td>7.0-7.9</td>
<td>13</td>
<td>12</td>
<td>1</td>
<td>0.92</td>
</tr>
<tr>
<td>8.0-8.9</td>
<td>15</td>
<td>15</td>
<td>1</td>
<td>0.94</td>
</tr>
<tr>
<td>10.5-14.2</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>1.00</td>
</tr>
</tbody>
</table>

* Patients were not treated according to protocol.
physical health as long as visual and mental capacities are effective. We must remember George Bernard Shaw's exhortation, as quoted by Nease: "Do not do unto others as you would that they should do unto you. Their taste may not be the same" (24).

The healthcare delivery system must develop an increasing awareness of the individual's desires for care. Patients must be encouraged to actively participate in care decisions. This participation will be most effective if patients have access to the best possible quantitative quality and outcome information (25).

Collaborative orientation. Autonomy in care decisions is eroding (26). Patients, payors, and providers must agree on the care process. They must also agree on what evidence is sufficient to support the decisions (2, 27). Evidence must be evaluated in a reproducible manner to yield guidelines for care that yield the expected outcomes (28).

Prevention orientation. Prevention is important to individuals as well as society. All individuals desire a long vigorous life with minimal terminal time in decline. Society would prefer for each individual to enjoy this long vigorous life with minimal terminal morbidity, thus minimizing care costs. Fries (29) has described the ideal rectangular survival curve for an optimally healthy population of humans (Fig. 2). To achieve the ideals of Fig. 2, we must postpone the onset of chronic diseases. Death is not preventable, but it may be postponable. Physiological decline is also not preventable but postponable. Fries implies that societal healthcare costs will be increased by lengthening survival if chronic diseases cannot be postponed. That is, lengthening life without postponing the onset of chronic disease lengthens the period of time in physiological decline (Fig. 3B).

In the past, healthcare was characterized by what I call "piecework profit." Providers were financially rewarded for providing specific care events, and rewards were increased if care was efficient. The future system will focus on prevention (i.e., postponement of morbidity), and financial rewards will accrue from improved health status in a population because services will not be needed (i.e., prevention profit).

We have studied outcomes among well individuals presenting for laboratory tests in public health fairs and voluntary employee groups (30, 31). These data indicate that sensitive thyrotropin (TSH) measurements provided to ambulatory well individuals will identify a new diagnosis in 1.2% and initiate a change in therapy in 1.1% (see Table 3). If the incremental cost of adding TSH to this testing activity is $2, the cost per benefited participant is calculated as $2000 to test 1000 people, benefiting 23 ($2000/23 = $87 per benefit). If the total charge for the whole testing program (including many tests) is $25 per individual, the charge per benefit is $25 000/23 or $1087 per benefit. Of course, the program may readily provide benefits in addition to those attributed to TSH, which would affect these calculations (30). Nonetheless, we have an obligation to understand the costs for benefits attributable to laboratory tests.

Cost of production orientation. Healthcare must be understood from both the macroeconomic and micro-

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**Fig. 2.** Possible biological limit to life in an optimally healthy population, as suggested by Fries (29).

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**Table 3.** Sensitive TSH assay in wellness testing

<table>
<thead>
<tr>
<th>TSH, mIU/L</th>
<th>0.05-0.23</th>
<th>0.24-0.9</th>
<th>10-20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (%)</td>
<td>31 (1.7)</td>
<td>19 (1.0)</td>
<td>42 (2.3)</td>
</tr>
<tr>
<td>Uncontactable</td>
<td>5</td>
<td>5</td>
<td>Not called</td>
</tr>
<tr>
<td>Ignored result</td>
<td>3</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>New diagnosis (1.2%)</td>
<td>2</td>
<td>1</td>
<td>16</td>
</tr>
<tr>
<td>Changed dose (1.1%)</td>
<td>12</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>No dose change</td>
<td>5</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>No MD action</td>
<td>4</td>
<td>5b</td>
<td>7d</td>
</tr>
</tbody>
</table>

* Total triiodothyronine = 189-244.

b Total triiodothyronine = 188-206.

c Long history of therapy with Synthroid.

d Normal concentration of free thyroxine.
economic perspective. We all hear discussions such as, "we found a way to get some of our patients out of the hospital a little earlier; we move them from an acute-care bed over to this hotel sort of function, and we save $400/day per person." The charge for that hospital day was $400; a hospital day did not occur. Someone did not pay the hospital that $400, or that $400 did not appear on the charge ledger. But did the hospital actually save $400? Of course not; the $400 charge was made up of allocations for debt, building and administration, and profit plus the cost of care. Only direct costs were saved. Those allocations need to be paid. In a micro sense, charge is a very poor proxy for cost (32, 33). We make unusual judgments because we confuse charge and costs. Complete analysis may show very little societal savings by changing the location of care (34). However, it might have short-term effects for a specific payor and a specific provider. Society must avoid the trap of thinking costs have been reduced when charges have merely been shifted.

Many financial databases have been constructed (16). These data are frequently used for quality and clinical purposes (35). Some of these studies have a clear clinical hypothesis (36). But we must remember that financial data may not be an appropriate surrogate for clinical data. Financial (utilization) data are always confounded by small area-specific variations (35).

**Value orientation.** In the past, local competition has frequently been characterized by duplication of facilities and "the medical arms race." Institutions have attempted to outdo each other with technology. If the previously discussed transitions occur, competition will move towards preservation of health status, not acquisition of equipment.

**Centralization?** There is a paradox. Healthcare institutions are seeking wider and wider mergers, while individuals attempt to retain personal choices. In the laboratory, we see mergers and simultaneous movements toward point-of-care testing. Are these trends, in fact, internally consistent? That arrow remains two-headed in Table 1. In which direction is this transition moving?

### Outcome Data Needed

The need for outcome data is the recurring theme when considering the forces and proposed solutions for the American healthcare question. When contributions in such diverse publications as Healthcare Forum (37) and Science (38) call for healthcare outcomes information, outcomes data must be important.

Not all seem satisfied with this new ascendency of statistical outcome data (39). We must remember that society will probably receive real-world "effectiveness" of procedures, which is less than the maximal potential "efficacy" observed in controlled clinical trials. Tanenbaum (39) states the case for clinical judgment. Has the trend toward outcomes assessment already overtaken the autonomous provider?

Laboratorians need to participate in assessing outcomes. Benefits attributable to laboratory procedures need to be identified. We must maximize the value we provide to others and not try to merely protect our turf. Has the theory of the laboratory business (40) moved to a new paradigm?

Healthcare is evolving. We are advancing past event-driven cost-avoidance mechanisms, such as utilization review, and into value improvement philosophies, such as total quality management, reengineering, and outcomes monitoring. When will the next evolutionary step occur? Will it be the movement toward healthier populations? Fries' hypothesis (29) suggests that the healthier population focus is necessary.

The evolutionary process in healthcare causes an ever-increasing accountability for costs and quality. This means we need better outcomes data now.

R.D. Schrantz and D.L. Wegner provided expert analysis for the data in Table 2.

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