Quality in Anesthesia Care:

Lessons from Industry and a Proposal for Valid Measurement and Improvement

Niels F. Jensen, MD

John H. Tinker, MD

1. Assistant Professor, Department of Anesthesiology
2. Professor and Head, Department of Anesthesiology

Address correspondence to Dr. Jensen, Department of Anesthesiology, University of Iowa College of Medicine, Iowa City, Iowa 52242. (319) 356-2633 No reprints available.

Running Head

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Abstract

Quality anesthetic care is a goal fundamental to our tradition and our training, but defining and measuring quality in anesthesia presents special challenges. Industrial models of quality, especially those so fundamental to the re-emergence of post-war Japan, deserve careful study and are discussed at some length, but they clearly have limitations in understanding quality in anesthesiology.

We suggest that most current quality efforts are inherently flawed. Whether or not they rigorously attempt to define quality, they are hampered by lack of data concerning outcomes and alternatives, as well as lack of distinction between quality and efficacy. Quality efforts in American medicine and anesthesiology seem mired in a "criterion of potential benefit,"which is still central to much of our prescriptions for individual medical care. Current quality improvement efforts do not seem well suited to correct these flaws.

Anesthetic care, and that of American medicine in general, is fragmented, enormously costly, and sometimes inappropriate and/or poor. Anesthesiologists are suspicious of current quality efforts to improve this care. The system often seems more geared to eliminate "bad apples" than to improve patient care.

Because anesthesia is a specialty which facilitates care but seldom "cures", we face greater challenges in studying and defining quality than do other specialties. Because of this, it is imperative that several principles govern future quality improvement efforts in anesthesiology. First, a reasonable balance must be attained between study of outcomes vs. processes of anesthesia care. Second, anesthesia-specific severity of illness indexing must be developed. Third, and perhaps most important, major volume protected national reportage of anesthetic processes and outcomes must be achieved. Fundamental to future quality efforts in our specialty, we believe, is the establishment of a protected National Anesthesia Outcome Registry. This communication reviews the industrial and medical history of quality, its measurement and improvement, and attempts to apply principles learned over many decades to anesthesiology.

Keywords

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Quality Model

Introduction

Three primary forces currently drive American health care policy, namely: efforts to control spiraling health care *costs*; efforts to assure and improve *access* to health care; and efforts to assure delivery of high *quality*, efficacious care. (Kizer 1990) The interplay and competition among these forces present unprecedented challenges for physicians, hospital administrators, insurers, and health care policy-makers. For physicians, the issue of quality should be paramount because it is central to the goal of achievement of the best patient outcome--a goal fundamental to our tradition and training. (Nelson 1990) Given the difficult challenges ahead for American medicine, it is imperative that the complex nature of quality in health care be understood and that the issues impacting quality be clearly defined. Ignorance, nonchalance, and/or defensive resistance will not enable physicians to contribute meaningfully to the current health care policy debate.

Defining and measuring quality in anesthesia presents special challenges. Our specialty does not "cure", but rather facilitates care. (Duncan 1990) As an extension of this, the risk of anesthesia is impacted by many other variables, including patient preexisting illness and the surgical process. Therefore, by what standards can we determine success or failure? What strategy of care produces the best outcome? What is "quality" in anesthetic care?

Industrial Quality

Current medical quality efforts can be better understood in the context of the recent history of industrial quality. Following World War II, Japanese products were generally shoddy and cheap. Today Japanese industrial quality is unsurpassed. (Winters 1990) A significant factor in this remarkable transformation was the adoption in Japan of ideas which had their origins in the United States, ideas ignored for many years by industrial leaders in this country. W. Edwards Deming and Joseph Juran, among others, formulated these ideas and were pioneers in advocating radically different approaches to management; approaches based upon production of quality goods and services. They contended that defects generally are

traceable to *systems* and *processes* rather than to *workers*, and that quality must be built into management processes so that the latter become predictable and lead to continuous incremental improvement in reducing waste, rework, and unnecessary complexity. (Berwick and others 1990b) Deming advocated a corporate culture of quality based upon controlling "upstream" processes, rather than correcting defects "downstream", to guarantee outcome, reduce variation, and continuously increase customer satisfaction. Deming defined quality as "delivering what the customer wants, the first time and every time"(Kizer 1990) . Central to this goal, he suggested, is liberation of human ingenuity and fostering of pride, purpose, and pleasure in good work. Definitely *not* a matter of adopting new sets of slogans or different means of accounting, the Deming quality strategy necessitated a radical restructuring of both systems and management attitudes. (Sensenbrenner 1991)

Deming urged use of "statistical signals" to detect flaws in systems or processes, with flaws then coming under attack and eventually being removed "one by one"(Duncan and others 1991) , making the goal of delivering "what the customer wants, the first time and every time," possible. (Kizer 1990) To achieve this quality objective, Deming's now-famous "fourteen points" (see Table 1) included: creating a constancy of purpose for improvement of product and service; ceasing dependence upon mass inspection; breaking down barriers between staff; instituting training and leadership; eliminating numerical quotas, slogans, exhortations, targets, and other barriers to pride; instituting vigorous and continuous programs of education and retraining; and improving constantly and forever all systems of production and service. (Duncan and others 1991) *

Despite many dramatic successes however, quality problems are still significant in American industry. It has been estimated, for example, that 20-40% of the expenditures of a typical American industrial organization result from correcting and preventing quality problems. (Eskildson 1991)

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* Todays students of Deming have considerable difficulty understanding why American managers were not doing these things all along.

Medical Quality Efforts

Although attainment of quality in health care is a "modern" goal, the expectation of quality care is probably as old as medical care itself. The Code of Hammurabi, circa 1900 B.C., sanctioned hand amputation for surgeons negligently inflicting permanent grievous injury upon their patients. (Couch 1991) Centuries later, a desire among physicians to standardize and improve the quality of patient care in the United States found expression in November, 1912 with the founding of the American College of Surgeons. The proposal, by Dr. Franklin Martin, leading to the creation of this organization at the Third Clinical Congress of Surgeons of North America stated: "some system of standardization of hospital equipment and hospital work should be developed, to the end that those institutions having the highest ideals may have proper recognition before the profession, and that those of inferior equipment and standards should be stimulated to raise the quality of their work. In this way, patients will receive the best type of treatment, and the public will have some means of recognizing those institutions devoted to the highest ideals of medicine. "(Roberts 1987) At about this time, the first standardized medical record was developed at Mayo Clinic by Henry Plummer. Codman first systematically audited medical records at the Massachusetts General Hospital in 1915, his efforts unfortunately neither accepted nor appreciated by his colleagues. (Laffel and Blumenthal 1989)

Despite the rebuff Codman received, quality improvement efforts by hospitals and health care professionals did slowly develop. In December, 1951, the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association joined the American College of Surgeons to create the Joint Commission on Accreditation of Hospitals as an independent nonprofit organization. (Roberts 1987) In the late 1960's and throughout the 1970's, because of increasing public pressure for physician accountability, millions of dollars and great energy were devoted to generating

"quality standards". Many physician and hospital groups convened panels, generated data, developed criteria, and became active in attempting to set guidelines and standards.

In the 1980's, although "standards" existed in some arenas of medicine, the new buzzword was "competition", but during this decade of unprecedented corporate and individual greed and supposed reliance on the "marketplace", it has become clear that "competition" neither assures quality nor contains costs. (Nelson 1990) In response, more studies were commissioned by Congress and other groups. The Omnibus Budget Reconciliation Act of 1987 mandated comprehensive assessment of quality assurance for Medicare. An amendment to the Public Health Services Act in November, 1989 established an Agency for Health Care Policy and Research (AHCPR) to create, review, and update "clinically relevant guidelines, standards of quality, performance measures, and medical review criteria." At about the same time, the Joint Commission belatedly began its "Agenda for Change", which, essentially, discarded its cherished "standards" and began to embrace Deming's insistence on continuous quality improvement. The AMA established its Office of Quality Assurance and began its Practice Parameters Partnership. (Nelson 1990) The American Society of Anesthesiologists is now busily developing practice "standards", "guidelines", and "parameters".

Hospitals and medical staffs questioned and complained about these external forces, which they often contended were not sensitive to regional or individual circumstances. Despite these problems, hospitals and physicians throughout the 1980's attempted to establish programs they thought would answer these outside demands for "quality assurance", as they struggled to define local practice standards and guidelines. It is fair to say that little of this activity was generated spontaneously from within these health care provider groups; most was in reluctant response to external pressure. Motives were most often, "how can we comply with their demands with the least disruption [change] for us?"

Insurance carriers became increasingly involved in administering and managing health care. Many large insurance corporations, including Prudential, CIGNA, AETNA, Travelers, Metropolitan, Humana, and Kaiser have developed or are in the process of developing national

"managed care networks", which are, basically, large preferred provider organizations with modern complexities. Prudential has invested over $300 million developing its network, which approves providers, negotiates reimbursement, and screens hospitals--all under the twin banners of controlling costs and improving quality. (Winters 1990) As the CEO of Prudential has orated, "We don't just write checks anymore. We manage care. . .Our goal is to manage the quality and appropriateness of care." (Winters 1990)

Industry has become disenchanted with spiraling costs for health benefits. In concert with their own relatively newfound understanding that real quality costs less, many corporations are now negotiating for "centers of excellence" (designated by them, not the providers) to provide "quality" at discounted rates, often procedure by procedure, disease by disease.

There is burgeoning interest among providers in applying to health care continuous quality improvement processes developed in industry. For example, Berwick et. al. at Harvard Community Health Plan, have been attempting to apply industrial quality improvement systems to medical quality care efforts under the auspices of the National Demonstration Project on Quality Improvement in Health Care. (Wyzewianski 1988) A preliminary report suggests that industrial quality improvement tools can be applied successfully to health care, at least to the extent that cross-functional teams are valuable in improving health care processes, but that involving physicians is difficult. (Berwick and others 1990c) This will be discussed below.

Medicine and Quality Problems

There are numerous major national and local quality problems in health care today. These are reflected by concerns of both patients and physicians regarding quality. Outcomes of care are generally unknown to the public (and to physicians), *especially outcomes after proven valid adjustments for disease severity*. There is the widespread perception of significant unnecessary and/or inappropriate care, as well as excessive variation, fragmentation, poor

coordination, and inefficient processes of care. Perhaps as a reflection of these issues, and also because of constant attention by the media and by organizations such as the American Association of Retired Persons (AARP), patients tend to believe they are paying too much for the care they are getting. They also are dissatisfied in large numbers with their perceptions of the overall quality of health care. (Schoenbaum 1990) Quality is in doubt. The human and technological successes of medicine are receiving less attention than its vulnerabilities and failures. The public is increasingly questioning the quality of medicine rather than celebrating its triumphs. (Berwick and others 1990b)

Physicians are concerned, even threatened, by suggestions of unnecessary and/or defensive and/or frankly inappropriate care, yet there is troubling evidence. *Per capita* hospital expenditures for seemingly comparable populations were reported to be twice as great in Boston as in New Haven. (Schoenbaum 1990) Several studies have shown that the care patients receive tends to depend importantly upon the particular physician who is treating them, with two to threefold differences reported in rates of test ordering, surgery, drug use, and hospitalization. (Berwick and others 1990b) For example, Wennberg et al. reported that in one Maine county 70 percent of women had undergone hysterectomies by age seventy, whereas in a nearby county, with quite similar demographics, that same figure was only 20 percent. (Berwick and others 1990b) In another study, 65% of carotid endarterectomies reviewed were considered questionably indicated, and 56% of the indications for Medicare-reimbursed pacemaker implantation were considered ambiguous or nonexistent. (Winslow 1988) Before prospective payment began, but with corrections for such factors as patient age, sex, and race, regional Medicare admission rates differed as much as 22 percent and lengths of stay by as much as 45%.(Bowen 1987) Whether or not these quality of care issues make patients less trusting and more litigious, it is a fact that in 1980, three of every 100 physicians had been sued by patients. By 1989, this had increased to eleven of every 100. (Berwick and others 1990b) In many specialties this figure is much higher today.

Such data questions quality and simultaneously emphasizes the increasing need for understanding, measuring, and improving it. Health care costs are inextricably linked to quality issues. The American health care system, by any measure, is the most expensive in the world. In 1989, the United States had a health care bill of about $605 billion, which more than doubled from $250 billion in 1980 and constituted about 11.9 percent of our entire GNP. By 1990, national health expenditures had risen to 12 of GNP. (1992) * During this same decade, other industrialized nations somehow held health care spending to well below 10 percent of GNP. (Reinhardt 1991) Current health care spending as a percentage of GNP is almost double the percentage obtained in 1965 and almost triple that of 1950. At the present growth rate, health care costs will *triple again* in 13 years. (Winters 1990) The cost of health care today continues to increase at nearly double the rate of inflation(Ackerman 1991) ; at current rates of growth, in the year 2000 spending is projected to rise to 15 percent of the GNP; by 2010 to 19 percent-- levels far above those likely for any other industrialized nation. (Reinhardt 1991) If the American health care sector of our economy was a separate entity, it would itself currently have the sixth largest "GNP" of all nations. (Berwick and others 1990b)

One of the most sobering aspects of these enormous costs of health care is that *beyond some point, there is unlikely to be any relationship between health care spending and medical outcome.* According to Reinhardt, "There is every reason to believe that the overall quality of American health care --and what economists call 'overall social welfare'--could be considerably improved at constant financial outlays, or even at lower overall health spending, if the real resources now deployed in only marginally beneficial or patently wasteful areas of health care could be redeployed toward activities located on the steeply ascending part of the cost-outcome curve." (Reinhardt 1991)

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* Whether or not health care costs should be evaluated as a <u>percent</u> of GNP is controversial. These comparisons cannot be easily corrected for our aging population, to say nothing about the effects of professional liability and the costs generated by defensive medicine. Also, our "health ethic" and our willingness to treat certain diseases, has not necessarily remained constant.

During the 1970's and 1980's, several strategies were tried to control these unbridled health care costs. These included fostering competition, limiting total payments, unit pricing (i.e., DRG's), efforts to encourage better management, and attempts to limit definitions of health care. None were successful. Not only did the strategies fail, but they contributed to new fears by various interest groups stating that access to, and/or quality of care was being compromised. (Berwick and others 1990b) Perhaps a reflection of this perceived erosion of available options and benefits is the fact that nearly 80 percent of all labor disputes in the past two years have been related to health care benefits. (Williamson 1991) From many quarters, the link between cost control and quality now seems quite tenuous. Amazingly, the question arises as to whether quality as a viable issue will survive (Berwick and others 1990b) -- especially when one considers other economic pressures on the system such as the cost of care for nearly 60 million Americans who are uninsured or under-insured. (Golenski 1991)

Medical personnel and lay people alike add to our difficulties of understanding and resolving these complex issues. The former are prone to obfuscation as well as to income-preservation bias, and the latter are prone to simplification and sloganeering. Adding to the problem are attorneys and legislators. They conveniently raise cost and quality issues whenever tort reform issues arise. (Trout 1990)

Many believe physicians need to educate better those who often do not understand or who easily dismiss the nature of medical costs. For example, in a recent address, the president of Prudential Insurance, the company mentioned earlier that hopes to "manage care", stated the following: "We are shocked to find the Pentagon spending $600 on hammers and $800 on toilet seats. But health care has similar problems. Recently a Florida man stepped on a splinter. He went to a local hospital to have it removed. When he received the bill he almost had to be re-hospitalized: $3,700. That's an expensive set of tweezers!" (Winters 1990) When there is no mention of diagnosis, treatments, or complications such "splinter stories" are at best simplistic, at worst unfair and inflammatory, and in neither case contributory toward resolving these complex issues.

Hospital administrators and quality assurance experts use escalating costs in medicine to justify programs to improve quality. Less often mentioned are the costs of administration itself, *which now amount to over 20% of the total cost of medical care*. (Schroeder 1987) Although administrators may find ways to cut costs and improve care, there is no doubt that they also generate expenses and help enlarge an ever-expanding bureaucracy. The cost effectiveness of many nonclinical health expenditures has escaped serious attention in the current policy debate(Himmelstein and Woolhandler 1986) but the growing size and influence of our health care bureaucracy has been noted by several observers. (Alper 1984) , (Morone and Dunham 1984) , (Himmelstein and Woolhandler 1986) Administrative waste is a significant drain upon the health care system. True benefits (both in terms of costs and patient care), of various quality improvement efforts, in either anesthesiology or other clinical areas, have not generally been proven-- despite claims to the contrary. (Brown 1984) , (Laffel and Blumenthal 1989)

Do we understand quality in Health Care?

What is quality? Some think the answer is apparent and others think it incredibly complex. Numerous concepts and approaches to quality assessment were promulgated in the 1930's, 1950's, and 1960's. Some believe that supporting the idea that quality in medical care cannot be adequately defined, allows us to continue to avoid troubling realities(Kizer 1990) and ignores more than a half century of work by pioneers such as Codman, Lee and Jones, Donabedian, and Williamson, to name a few. Others believe that the current interest in quality is an opportunity which should not be squandered by ignoring and / or re-inventing that which has been learned in the past. This subject includes how quality can be defined and measured, but also the relationships (if any) between outcomes and processes of care as well as relationships between quality and efficacy. (Wyzewianski 1988)

Quality of medical care has been defined in many ways(Kizer 1990) , (Reinhardt 1991) , (Berwick and others 1990a) , (Palmer 1988) , (Donabedian 1988) but there is agreement that it

should include relative assessments of potential patient benefits vs. harms plus achievement of both patient and physician goals. (Donabedian 1966) , (Steffen 1988) Donabedian, a leading thinker about modern medical care quality, (Laffel and Blumenthal 1989) defined quality of care in medicine as "that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts." (Donabedian) The JCAHO defines quality as "the degree to which patient care services increase the probability of desired patient outcomes, and reduce the probability of undesired outcomes, given the current state of knowledge".(Robinson 1988) Despite these high-sounding definitions, clinical practice is often complex, unpredictable, imprecise, and incomplete. A definition of quality and its accurate assessment is elusive, especially in a field such as anesthesiology, for many reasons addressed below. (Donabedian 1988) , (Wyzewianski 1988) , (Bowen 1987) Medicine remains art in many aspects. Efforts to define and assess quality must take that fact into account. (Donabedian 1988)

Donabedian's classification of various quality of care studies into evaluations of *structure*, *process*, and/or *outcome* has been widely accepted. (Donabedian) , (Wyzewianski 1988) Structure denotes attributes of the settings in which care occurs. Process describes and evaluates what is actually done in giving and receiving care. Outcome defines effects of care on the health status of patients and/or populations. (Donabedian 1988) These are neither distinct nor mutually exclusive but are instead connected and interdependent. (Wyzewianski 1988) , (Lohr 1988) According to Donabedian: "This three part approach to quality assessment is possible only because good structure increases the likelihood of good process, and good process increases the likelihood of a good outcome." (Donabedian 1988) * Emphasis placed upon each of these aspects may change with the times. Indeed, as concerns about quality evolved from trying

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* It is widely believed that flawless, even good, process should lead to good outcome. Because expectations have been driven so high, poor outcome indicates process fault and/or human error to many people. This notion is not tenable, given our imperfect understanding of most disease processes, and our similarly imperfect understanding of how drugs and other treatment interact with disease and each other.

to determine whether money was well- spent, which was the emphasis of the 1960's and 1970's, to present concerns that quality may need to be compromised (or rationed) because of costs, emphasis has shifted from structure and process to outcome.

Sometimes it is difficult, even for experts, to keep pace with changing times. (Nelson 1990) For example, when JCAHO, with its historical focus upon structure and process, found itself ill-equipped to respond to concerns about under-provision of care raised after the institution of DRG-based payment, it shifted to an outcome-based strategy. (Wyzewianski 1988) "Standards" and "monitors" of outcome were voluntarily set, and then JCAHO inspected for compliance. Not only were they voluntary, these standards and monitors were static. Most recently, JCAHO once again found itself outside the "continuous quality improvement" thinking now taking hold in health care. That organization is now busily modifying its emphasis on standard-setting and "monitors" of just a few years ago, as it institutes its "Agenda for Change". Federal and state governments have entered the outcome arena, which has resulted in publication of hospital-specific, DRG-specific outcome data supposedly adjusted for severity of illness. Hospitals at the top of the lists strut and gloat while those at the bottom cry foul, especially on severity of illness issues.

Quality vs. Efficacy

Not only has the focus of quality effort historically varied, quality improvement has traditionally been hampered by confusion between quality and efficacy. Valid *quality assessment* studies should determine whether treatments or interventions which are already known to be appropriate and efficacious have been selected and performed with skill and competence. Quality studies should answer the question: "Was the right thing done, and was it done right." Efficacy studies, on the other hand, answer a different question, namely: "What is the right thing to do?" Efficacy reflects benefits under "ideal", clearly defined conditions. (Lohr 1988) Efficacy studies establish whether a drug, procedure, or intervention has the best

and most desirable effect compared to other possible or available treatments. Thus, quality determinations require *a priori* knowledge of what is efficacious. (Wyzewianski 1988)

One would think this is obvious, but it is not. This distinction is not just an academic nuance. There are major implications. An example: the setting by individual hospitals or surgical organizations of "standard indications" for "emergency" coronary bypass graft surgery, when the efficacy of the operation itself, for many "indications", especially emergency ones, is not established* . In many health care settings, local practices soon become "standards", which then are held as "monitors of quality". Efficacy gets conveniently eliminated from consideration, i.e. if a treatment is now an *established* standard, it must be efficacious. *This is one of the costliest traps into which American medicine has (willingly) fallen.*

The establishment of quality should rest upon a firm foundation of efficacy; we need to know what "right" is *before* we can determine whether the "right" thing was done and whether it was done "right". Unfortunately, the determination and scientific foundations of efficacy in many if not most health care areas are tenuous. For many therapies and interventions, the outcomes of what physicians do, the appropriateness of alternative management strategies, and the relationships between processes and outcomes(Lohr 1988) are simply not known. Efficacy, in other words, has simply not been established.** According to the Institute of Medicine, valid randomized controlled efficacy studies have been applied to only a very small part of medical practice. Almost no surgical procedures or technology have been evaluated as to their effectiveness under average conditions. (Institute of Medicine 1985) Wennberg, in commenting upon the two to threefold variation in the use of some medical and surgical procedures between various regions, argued that in the absence of firm evidence of

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* Either for prolongation or "quality" of life.

** An equally disturbing problem is the all-too-ready acceptance, by critics of health care providers, of the null hypothesis, i.e. if efficacy has not been clearly established for a treatment, then it must not be efficacious. This is a dangerous tendency toward therapeutic nihilism which has resulted in "alternative therapies", a modern name for quackery.

efficacy, expert medical opinion has no choice but to accept as appropriate a broad set of indications for treatment. (Bunker 1988)

Unfortunately, many physicians are all-too-willing to accept the status quo, i.e. that such a dearth of legitimate evaluation of efficacy, especially of surgical procedures (and their enabling anesthetics), must continue because of the basic nature of surgical therapies. Many surgeons believe that that which is mechanically logical must be efficacious. It is mechanically or even physiologically logical to bypass partly or completely obstructed coronaries, but there is considerable evidence now that the atherosclerotic process is actually accelerated in the bypassed vessels and that same process now begins in the vein or arterial grafts as well. Life is not, on average, lengthened by the procedure except in specific subsets of the population currently being subjected to the procedure. Valid efficacy studies of many widely performed procedures might jeopardize whole segments of practice, i.e. true "industries".

Numerous well-accepted conventional treatments have recently been examined by Eddy to learn if valid efficacy studies exist regarding recommended practice or alternative managements. (Eddy 1990) The treatments studied included the following: ambulatory blood pressure monitoring; gamma globulin to treat Kawasaki's disease; tympanostomy and tubes for otitis media; driving restrictions for patients who have seizures; antibiotics for questionable Lyme disease; prenatal screening for HIV infection; work-up of women with breast masses; Caldwell Luc procedures for maxillary sinusitis; treatment of recurrent bladder cancer with BCG; prophylactic antibiotics for patients who have mitral valve prolapse and require dental procedures; CT and MRI scans for evaluation of headaches; pulmonary arteriography for patients with suspected pulmonary embolism; radiation treatment for prostate cancer; and pulse oximetry for patients undergoing conscious sedation. After exhaustive literature searches it was concluded that none of these have been evaluated with well-designed, controlled studies comparing alternative interventions. The truth is that many currently "standard" diagnostic

and therapeutic practices, involving huge numbers of patients, high risks, and tremendous costs, rest upon very uncertain foundations with respect to efficacy. (Bunker 1988) , (Eddy 1990)

If we are uncertain about outcomes in large populations of treated patients, we cannot establish statistically or clinically valid efficacy. Without valid knowledge of efficacy we will continue to have major impediments to understanding and improving quality. Therefore, attention to the basics of outcome and comparisons to alternative management is imperative. (Lohr 1988) , (Bunker 1988) According to Wennberg, "It is of extraordinary importance to evaluate reasonably held, but inadequately tested, theories of treatment of common illness. . .The task is manageable: 23 operations cover 60 percent of major surgical admissions to U.S. hospitals and about 40 acute and chronic illnesses make up about 70 percent of medical admissions." (Wennberg 1987)

Although others are less optimistic, (Bunker 1988) it is likely that this will require more than just better use of technology and improved data collection. It will require what Eddy has characterized as a dramatic change in the way individual medical decisions are made, namely a shift from a "criterion of potential benefit" to a "criterion of actual benefit".(Eddy 1990) Eddy argued that medical decisions have traditionally been made on the basis of *what might possibly or logically be of benefit*. This standard is based upon theory, analogy, personal experience, and anecdote and is generally justified as being part of the "art of medicine." Real benefits, costs, outcomes, and alternatives can then be largely ignored, because most activities that might possibly have benefit can then be justified and therefore will be performed. (Eddy 1990) This, basically, is our current mode, namely "I'm the doctor, I'm the patient's independent advocate, and I know what is best."

This approach is seductive and costly. Many medical activities do have some benefit, and each is performed one patient at a time, i.e., the patient rarely has the simultaneous opportunity to try <u>two</u> therapies. Thus, the "criterion of potential benefit" is perpetuated. One should not underestimate the seductive power of this criterion. It has ruled medical practice since its beginnings and still largely does. This criterion is automatically biased economically

in favor of its perpetuation. This perpetuation does little to stimulate research or systematic analysis of outcomes and efficacy which are the real foundations of quality.

There is another reason why physicians apply the "criterion of potential benefit", namely the fact that it is, by far, the path of least resistance. Doing that which is "standard" and "logical" does not require an up-to-date knowledge of pertinent outcome literature. Lawyers meticulously research *their* literature for *each client*. Doctors all too often, do that which is "logical" or "standard". The costs of this "criterion of potential benefit" are staggering, and our economy staggers under them. Physicians clearly want to believe they are doing the "right" things for their patients, when much of the time we actually wander in the desert of uncertainty. We should not be surprised that our care, as noted above, is so often fragmented, poorly coordinated, and even frankly inappropriate.

A flagrant current example of the "criterion of potential benefit" can be found in some cases of organ transplantation. In 1990, a 26 year old Pittsburgh woman became the first person to receive a new heart, liver, and kidney in the same operation. She had a long history of heart disease and had undergone a prior heart transplant (i.e., this was number two). At Pittsburgh Presbyterian Hospital, 11 surgeons, 6 anesthesiologists, 15 nurses, a physician's assistant, 2 blood technicians, and a liver technician worked for 21 hours to accomplish these transplants. These skilled and experienced people *without a doubt* applied every bit of their immense pool of talent, to their very best abilities-- as did the equally skilled team that continued her critical care. Despite their heroics, she died after 113 days of intensive care. According to her father, "They tried to make her life better but she suffered for four months in the hospital and nothing was accomplished." The bill to her father's employer was $1.25 million. (Winters 1990) Just because we apply a "criterion of potential benefit", can we continue to spend limited resources on the terminally ill when millions are denied basic health care coverage? The money spent on that single patient's care would have bought 30,000 measles inoculations (there were 45 child deaths in the U.S. from measles in 1989), prenatal care to 1,000 women, or cereal allowances for one month to 250,000 one year olds. (Winters 1990)

In medicine, we work very hard. We put in long hours. We care about our patients and their families. All of this is to our great credit. Our key point is as follows: the *very facts* of our hard work, dedication, long hours, and yes, even sacrifice, *tend to convince us that we are doing good.* Our whole system is set up to bias us in the direction of "lets *do something*"; and, while we are doing "something", we *desperately want to believe* we are doing good because we do care deeply about our patients. Often, we do a magnificent job of convincing ourselves that this is so. This well-intentioned but unfortunately often invalid way of doing our business is, we believe, *the single most important long term correctable reason for the staggering escalation of health costs.*

In the true example from Pittsburgh above, if each of the professionals involved had instead administered her / his share of the 30,000 measles inoculations mentioned above, the *patient* would have had her life end with more dignity, 45 child deaths might have been prevented, and these health care workers would likely have had to work fewer hours (although they might not have had the excitement that comes from "pioneering").

A "criterion of actual benefit" does not require that *every* treatment be known to be efficacious before it is administered. It does require that we continuously pursue approaches which can be reasonably expected to lead to knowledge about efficacy, namely outcome and comparative alternative assessments plus valid weighing of benefits versus risks and costs. This will allow us to collect and assess evidence for what we do and continually to reduce uncertainty--placing us in better positions to make informed decisions. (Eddy 1990) Many say "how can you deny the obviously logical treatment we are [empirically] doing just in order to have a 'control' group?" Coronary artery bypass grafting, which is superficially logical as a plumbing solution, is just such an operation that was *not* subjected to valid efficacy studies during the years when such could easily have been done. For an in-depth review of the history and developmental validity of this particular operation, which grew into an industry, the reader is referred to the elegant work entitled "Coronary Artery Surgery: a critical review", by Thomas Preston (Raven Press, 1977). CABG is now an "industry" that developed with few

valid efficacy studies along the way. More recently, as coronary angioplasty emerged as its own industry, cardiologists who had previously been critical of surgeons did not perform their own valid efficacy studies of angioplasty. They too were seduced by the "criterion of potential benefit". In today's operating room, everything that remotely can be done with a "scope" and a TV screen is being done. (e.g. laparoscopy, arthroscopy, thoracoscopy, performing meniscectomy, herniorrhaphy, cholecystectomy, tubal ligation, lung biopsy, etc.). Few efficacy studies are even contemplated. Whether this current fad is justified from a standpoint of efficacy is not known. It likely is more costly.

Quality Assurance vs. Total Quality Management

This is precisely where most hospital and department based quality improvement efforts so often fall short. Quality programs generally have three major foci: assessing or measuring performance, determining whether performance conforms to "standards", and improving performance when "standards" are not met. (Laffel and Blumenthal 1989) Quality Assurance is a systematic process for evaluating the main elements of medical care (structure, process, outcome). The components are identifying indicators, establishing criteria, and gathering data from clinical activities. (Eichorn 1989) Total Quality Management, which is better termed "continuous quality improvement", began in the early 1980's to apply the methods by which Japanese industries had achieved such rapid and dramatic success in simultaneously improving quality and productivity. Important components include: commitment to an unrelenting focus on customer* satisfaction, continuous improvement, employee involvement, "management by fact" (including use of statistical process control), effective internal and external teamwork, emphasis on *prevention of defects* rather than *inspection for defects*, cycle time reduction, and widespread staff training in areas affecting quality.

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* By "customer", the Deming philosophy means either "internal" or "external" customers. In health care, the external customers are the patient and family. The internal customer might include the surgeon, if OR turnaround time can be improved.

(Eskildson 1991) In all of these, learning more about alternative treatments and analyzing comparative outcomes unfortunately seems lacking. This greatly adds to the difficulty in specifying the components of quality in ways that can be effectively employed in control processes. (Vladeck 1988)

In terms of such processes for physicians, quality improvement programs ultimately collect and monitor data continuously and, when warranted, try to modify individual physician practice behavior. Although there are guidelines designed to protect physicians, (Service 1988) unfortunately, zealous efforts to collect data and to single out individuals for "remediation" can replace attempts to establish efficacy of treatments and procedures. The latter generally would be welcomed by physicians to help guide their decisions and are necessary before final quality determinations can be made.

Because the underpinning of quality is efficacy, but efficacy validation is so uncommon for surgical procedures and/or anesthetic and monitoring techniques, it is not surprising that many physicians question the fundamentals upon which "quality assurance", "quality management", or "total quality control" appear to be based. Physicians have strongly resisted these efforts, either because they represent perceived threats or for the better reason that efficacy foundations are often lacking. Garvin suggests the following reasons: first, doctors may resist measurement because it has often been associated with policing activities; physicians are suspicious that measurement allegedly intended for improvement might instead be used for surveillance and/or judgement. Second, there is substantial resistance to standardization, partially because of the belief of many physicians that the practice of medicine is an art, but there is also considerable reaction formation, i.e., finding some other method than the "recommended way". Third, resistance is associated with perceived loss of autonomy. Proceduralizing, i.e. development of formal ways of performing tasks, is contended to limit freedom to diagnose and prescribe. (Garvin 1990) Although all of these are relevant, for many the first and the third are especially important today. Most hospitals are now heavily engaged in the business of competing for patients. They control the data acquisition and

interpretation upon which "quality efforts" are based. Because hospitals can generate interpretations which can ultimately be used to modify the behavior of doctors, many physicians perceive potential conflict of interest.

With outcomes, alternatives, and efficacy so often in doubt and with Quality Assurance, Total Quality Management, and other institutionally-based programs in vogue and on the increase, resistance by physicians to accept and participate in "quality improvement" efforts continues and even grows. Resistance also continues both because of training physicians do not receive and training they do. Medical schools, by and large, have not chosen to integrate quality improvement training into medical school curricula. Hospitals run residency programs, and do not generally include such training either. (Ackerman 1991) The education and training physicians do receive is long, rigid, very often dogmatic, and can even be tyrannical. Does the typical senior physician-teacher really listen to the student or resident? Training is often antithetical in concept to that which Deming advocated, namely recognizing and unleashing ingenuity and potential. With a system so rigid and hierarchical, is it possible that the caring, humanistic, and empathetic aspects of medicine which initially attracted most students have been lost or at least downgraded in physician interactions with patients, employees, and peers? Is it possible that the policing activities which clearly characterize many Quality Assurance activities, and which many naturally though incorrectly perceive to continue with Continuous Quality Improvement, are in some ways a re-creation of the threatening and restrictive environment of medical training? Buzzwords like “physician-specific QA” are antithetical to the Deming teachings; he said “break down barriers”. Such policing, under the completely anti-productive but often heard statement “if we do not do it, someone will do it for (to) us”, has clearly proven a dismal failure -- as was understood by Deming 40 years ago. Much current QA activity bears uncanny resemblance to the assembly-line foreman who says "I <u>know</u> you workers are trying to cut corners, loaf and cheat. When I catch you, I'll hammer you!" We

find it sad that our “voluntary”* JCAHO is just now beginning to embrace Deming's continuous quality improvement principles, but still wants individual physician-specific credentialing files, documentation of incident report investigation and evidence of disciplinary action, etc.

Quality, Outcome, and Processes in Anesthesia

Anesthesiology was one of the first medical specialties committed to a systematic, widespread, and statistical understanding of quality. This took the form of the ASA Physical Status Classification, first proposed in 1941. The intent of this system was to "correlate the relationship between result, the operative procedure and the patient's preoperative condition." (Saklad 1941) Other subsequent grading systems, such as that by the American Heart Association, had the same purpose. The original classification contained six groups with "systemic disturbance" graded from none to extreme. (Keats 1978) Ironically, while the system was not designed to estimate "operative risk", its use over more than fifty years has revealed it to be an excellent predictor of overall surgical mortality. (Marx and others 1973; Vacanti and others 1970) Problems with the ASA Physical Classication will be discussed below.

Anesthesia, as noted above, is a specialty which facilitates care but seldom "cures".(Duncan 1990) This diminishes neither the importance nor the role of our specialty. The emergence and development of anesthesia is as important as any development in the history of medicine. Although our technology, training, and skills make possible radical interventions and near-miraculous cures, because anesthesia seldom cures disease, the challenge of precisely defining anesthesia quality is inherently difficult.

Consider outcome assessment, for example. Inherent problems related to outcome assessment and the role of anesthesia include separating the occurrence in question from patient illness, the surgical process, and other significant variables. (Charlson and others 1986) ,

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* The notion that JCAHO inspection is voluntary and invited by the hospital strains credibility, because so many payment mechanisms, especially Medicare, are contingent upon JCAHO approval. "Voluntary"? No.

(Hughes and others 1987), (Dubois and others 1987) This does not imply that we should cease to attempt measurement of outcomes, but we must appreciate the complexities. Because positive results from an anesthetic standpoint are overwhelmingly likely to occur, other crucial measures of outcome and of quality in addition to traditional measures such as anesthesia-related mortality must be created and evaluated.

For anesthesia-related activities, it is necessary to shift from a focus solely upon *outcomes* of care to one which also carefully considers *processes* of care. As is true with all medical care, the consequences of anesthesia care may prove disastrous despite the fact that care may have conformed to "standard" practices and processes whether efficacy has been established for them or not. (Donabedian 1988) Adverse outcomes do not necessarily imply poor quality of care for a number of other reasons, among them the well known wide biologic variation in responses and interactions between anesthesia and pre-existing severity of illness. Meaningful comparisons of anesthesia-related outcome require adjustment for severity of illness(Dubois and others 1987) and careful scrutiny of all care processes. A critical difficulty is that severity of illness adjustments are not refined to the point of being able to add validated *anesthesia-specific* risk factors. For example, the 40-year-old healthy patient scheduled for cholecystectomy may have no real overall medical risk factors, but can present a significant anesthetic risk if he has a badly underslung jaw, thick muscular neck, and large carious upper incisor teeth. Further, most would agree that a patient who suffers no adverse outcome despite experiencing a "critical incident" during anesthesia *may not* have received good quality care; (Duncan 1990) the outcome was acceptable and yet the processes and thus the quality of care were not. Therefore, assessment of quality in anesthesia must heavily focus on process.*

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* We said earlier that the foundation of quality is efficacy. If we render our patients unconscious, is that not efficacy? If so, is that not quality? The airlines face the same difficulty. The passengers walk alive back into the terminal at the end of the flight, at their correct destination. Is this not efficacy? If efficacy is the foundation for quality, then is this gross outcome sufficient for a determination of quality? Obviously not. There could have been several critical incidents, departure from ageed-upon procedures, near misses, etc., along the

Although processes are important and do play roles in quality determinations, outcome assessment remains crucial despite the problems mentioned. Unfortunately, anesthetic outcome studies have traditionally been narrow in scope(Holland 1987), (Lunn and others 1982), (Hovi-Viander 1980) or obviously biased, as with closed claim analysis. (Duncan 1990) We perform about 26 million anesthetics yearly in the U.S. alone, yet recent outcome studies involving more than 1,000 patients, and/or involving more than one center, are nearly nonexistent. Outcome analysis should determine what happened and why and should be governed by four principles, according to Vitez: 1) it must be continuous and collective; 2) it must be conditional, given the wide range of clinical practice; 3) it must be comparative; and 4) it must establish minimum standards. As an example of the latter, very healthy (ASA 1) patients should not suffer organ damage or death. (Vitez 1990)

It has been suggested that outcome analysis may facilitate error analysis and judgments about competence. There are, according to Cooper, three types of human errors: judgment errors, technical errors, and vigilance errors. (Cooper and others 1984) One measure of competence is the number, type, and severity of errors corrected for number of cases and, hopefully, indexed for anesthesia-specific severity of illness. Error analysis would theoretically allow creation of a Departmental profile and comparative assessments of care provided by each individual. Unfortunately this leads to the perception of threat and all the consequences thereof. Specific models to perform and conduct error analysis within a department of anesthesia's quality assurance program have been suggested. (Vitez 1990) In addition to the threat perception, the other major problem is how to construct the denominator, namely not just number of cases, but the caseload corrected somehow for valid anesthetic risk

We are making an assumption here for which no evidence exists. We are assuming that simply making a fraction wherein some sort of number of critical incidents would constitute a

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way. It is nonetheless valued, even though we in anesthesia (and the airlines) must focus upon process, to *test our processes* continually for evidence of efficacy. A focus upon process does not negate the fact that the foundation for quality must still be efficacy.

numerator and total number of cases would be the denominator *would not* be valid. It seems to us that the denominator should be adjusted for anesthesia-specific severity of illness. The anesthesiologist who performs anesthesia for many ASA-1 patients should perhaps be expected to have almost zero “critical incidents”, and the denominator (total number of cases) will be quite high unless adjusted somehow for severity of illness, compared to the anesthesiologist who performs complex anesthetics on critically ill patients for similar numbers of hours, but with a far lower number of cases. This kind of a measure of competence or quality, i.e. the number of critical incidents divided by total number of cases, adjusted somehow for severity of illness using anesthesia specific criteria would still have problems. For example, if "critical incidents" are to constitute a numerator for a measure of competence, then reportage of these incidents will drop precipitously, eventually leveling off at a value near to that which would obtain if outside observers, e.g. circulating nurse or surgeon, alone reported the incidents.

Mortality, the traditional measure of outcome, is too crude to assess anesthetic care. The most recent Confidential Enquiry into Postoperative Deaths from Great Britain, which examined perioperative deaths in the National Health Service over a 12 month period, reported a very low death rate from anesthesia (1: 185,000 operations), but the reporting was voluntary. Even in Great Britain, fear of legal action is on the increase, therefore how much "improvement" was real vs. how much due to lower actual reportage? (Buck and others 1987) Cohen and Duncan evaluated mortality in 112,000 patients served in Winnipeg over a 10 year period and reported that advanced age, male gender, physical status, major surgery, emergency surgery, intraoperative complications, and narcotic techniques were associated with increased mortality. In sharp contrast, they reported that duration of anesthesia, experience of the anesthesiologist, and inhalation techniques were not associated with anesthesia-related mortality. Anesthetic factors which were related to mortality were much less important than patient and surgical variables. ASA physical status did appear predictive of overall mortality, but not of anesthesia-related mortality. (Cohen and others 1988) Note that all

these studies were performed on populations outside the U.S.. Our litigious population and system of discovery in the U.S. clearly stand in the way of valid understanding of both the incidence and causes of our real anesthesia-related outcomes. Retrospective closed-claims analyses are fascinating, but they only include that population of patients (plaintiffs) in whom contingency fee-based lawyers can expect large potential gains. This effectively excludes elderly patients, among others.

The many studies on perioperative mortality contrast with the relative dearth of research on anesthesia-related morbidity. One of the largest of the latter was a study from France which evaluated 460 institutions between 1978 and 1982. Preoperative factors associated with occurrence of complications were ASA physical status, age, surgical procedure (major vs. minor), and type (elective vs. emergent). Fifty-eight percent of complications occurred during anesthesia and surgery whereas 42% occurred post-operatively. Most frequent was respiratory depression, but France in those years still had a relative dearth of recovery room facilities. (Tiret and others 1988)

Duncan et al., in 1987, reported that risk increased with anesthetic duration and physical status but was not influenced by the surgical procedure. Use of spinal or epidural techniques were associated with greater morbidity than inhalational techniques. Anesthetist experience was a factor in reducing postanesthetic complications. (Duncan and Cohen 1987) This is in sharp contrast with a study by Yeager et. al., also in 1987, who found that high risk surgical patients who received intraoperative combined regional (epidural)/general anesthesia plus epidural postoperative analgesia had reductions in the incidence of cardiovascular failure, major infectious complications, hospital costs, and overall postoperative complications. (Yeager and others 1987)

Not only because of inherent problems in defining quality in anesthesia, but also for other reasons, determinations of clinical competence are complex. For example, anesthesia is one of numerous arenas in which there are actively practicing non-physicians competing directly with physicians, CRNAs vs. anesthesiologists, nurse midwives vs. obstetricians;

chiropodists, podiatrists and chiropractors vs. orthopedists; psychologists vs. psychiatrists; “alternative therapists” vs. family practitioners and internists; physician assistants and nurse practitioners vs. pediatricians, internists and family practitioners. The problem of understanding quality now becomes politicized with the volatile question: how much and which part of each of these practices really is safer and/or better, with provably better results if done by the physician? Physicians who are up against such non-physician competition are even more threatened by efficacy, safety, or quality studies in areas where their practices may overlap with non-physicians.

In anesthesiology, negative anesthesia-related outcomes can be generally categorized into two overall groups, namely negative outcome related to: 1) problems with medical knowledge, skill, experience, or training; vs. 2) problems with vigilance, wrong drug, errors, lapses, corner-cutting, attitude, drug abuse, etc. If large, provider-specific, severity of illness corrected, anesthesia outcome studies could be done, and if, as seems possible, the majority of problems are in category 2 above, then physician-anesthesiologist-related severity-adjusted outcomes vs. those of non-physician anesthesia providers may <u>not</u> necessarily be better. We make these statements merely to underscore the fact that quality determinations are extraordinarily complex and political in anesthesiology. We will present below a plan as to how this dilemma might be approached. It is arguable whether any small set of data, no matter how collected, can determine "clinical competence" or quality with projectable validity.

Further, determinations geared to eliminate "bad apples"(Berwick 1989) are not consistent with the principles advanced by Deming, Juran, and other modern industrial quality experts and simply do not work. This "theory of bad apples" holds that problems can be traced to individuals and to their ignorance, laxity, and/or sloth. The theory further contends that improvement is somehow possible via threats and/or sanctions. This outlook leads to a search for better tools for inspection, establishment of thresholds of acceptability, and identification

of outliers, but does not support workers (including physicians), the vast majority of whom are trying to do their best. (Berwick 1989)

Thus it is possible to create a more efficient system of measurement but a less effective one. Deming said "drive out fear". No system of process evaluation in anesthesiology can easily overcome the fear of those whose performance it is purported to measure if sanctions and other policing activities are based upon the results, because the reportage is largely under the control of those who will potentially be sanctioned. If the system attempts to find deficiency and administer punishment, subjects will endeavor to prove they are not deficient and thereby avoid the wrath of the system. Playing defense, can take the form of not reporting data, altering or destroying it, or diverting attention from it by turning-in someone else. (Berwick 1989) The Japanese worker believes he/she will not only avoid punishment, but will be rewarded if reports of performance are accurate because management will work with the worker to try to improve the system or process. This concept, in our opinion, has not even begun to penetrate U.S. medical system.

Policing and resultant defensive tactics proved disastrous to American industry by the 1960's and 1970's. These tactics have not helped anesthesiology in the 1980's. Perhaps the best hope for real quality improvement is through the same basic approach used so successfully to re-industrialize postwar Japan--*a strategy of continuous improvement*.* The foundation for this strategy is that quality problems are usually built into production *processes* and are not due to sloth, neglect, or malevolence of people. An environment of fear must be replaced by one of analysis, concern, and education. A problem must be treated as an opportunity to discover the mechanism of an imperfection and then as a chance to improve. If these tenets can be placed as

* One of us (JT) came away from a trip to Japanese departments of anesthesia convinced that Deming/Juran et.al. did not appreciably influence Japanese anesthesiology; a hierarchy exists in some areas which can still be described as "medieval". Japanese medicine in general or anesthesiology in particular does not use Total Quality Management.

foundations for quality improvement efforts in medicine and anesthesiology, the potential for real improvement is vast.

A Plan for the Future

In order to evaluate medical quality we must first understand what it is and what determines it. Many of the common definitions of medical quality have features which are valid to us in this context, yet their focus is often broad and their applicability to anesthesiology limited. In fact, as noted above, it is difficult to measure quality in anesthesia, for a number of reasons. We believe that a formal plan for the future of quality development in anesthesiology is needed--a plan which is far-reaching, with great potential, and yet is specific to our needs. Central to such a plan is a National Anesthesia Outcome Registry.

What is wrong with the existing, time-tested ASA Classification of Physical Status? As noted above, while it does correlate to overall surgical mortalilty and still, after fifty years, constitutes one of the best indices of operative risk it is not anesthesia specific. According to Authur Keats, for example, the system "does not estimate the risk of malignant hyperthemia, inability to intubate the trachea because of deformity, inadvertant esophageal intubation, hypoxia by machine malfunction, the risk of uncontrolled hemorrhage, mismatched transfusions, or the performance of more radical operations than planned. About the only mechanism of anesthetic death that could correlate with Physical Status is 'overdosage'. . .The system is subjective, intuitive, and vague." (Keats 1978) Owens et al. concluded that the system "is useful but suffers from a lack of scientific precision." (Owens and others 1978)

Fundamental to an understanding of anesthetic quality is anesthesia-related negative outcome. We cannot improve the former without detailed information about the latter. We suggested above that negative anesthesia outcome can be considered within the context of one of two broad categories: First, lack of or failure to apply knowledge, skill, training, and/or expertise--didactic or practical; second, errors of vigilance, lapses, sloth, errors of omission, and/or succumbing to expedient but not necessarily safer courses of action (i.e. corner cutting).

In order to understand the relative importance of each of these two categories, an understanding which holds the key for improvement in outcome and thereby quality, an evaluation of the overall nature and extent of anesthetic morbidity and morbidity is necessary. Next, we must understand, quantitatively, who delivers anesthetic care in the United States and discover what anesthesia care delivery system is safest and best for the many procedures for which we anesthetize or sedate patients. Should there be an anesthesiologist one on one with a patient, a nurse anesthetist supervised by a Board certified anesthesiologist, a nurse anesthetist supervised by a non-Board certified anesthesiologist, a nurse anesthetist supervised by a surgeon, a resident supervised by an anesthesiologist, or a PA or GP with or without formal anesthesia training? We must learn how much anesthetic morbidity and mortality occurs in America today, what causes it, and how education or training can improve it? The data necessary to make valid conclusions have never been collected, let alone analyzed.

Data are lacking partly because a valid anesthesia specific, severity of illness adjusted scoring system does not exist. Although massive efforts have been made to develop overall severity of illness indexing, and data bases exist which include millions of patients, such indexing is almost totally lacking in our specialty.

Without it, our focus upon process outcome and final outcome, the fundamental parameters of quality improvement, will be at best blurred. What factors determine anesthesia-related outcome? They must be multiple but there may be relationships and commonalties among them which would provide keys of enormous importance for quality improvement. Without data we simply do not know. Therefore, we can not effectively implement educational programs. We do not even know whether we should emphasize our first category of outcome mechanisms, namely knowledge and skills, or our second group, the attitudinal ones, primarily concerned with vigilance and motivation.

A plan for the future must include serious efforts to determine, in a protected way, anesthesia outcome in America in the 1990's. Holland, over a period of twenty-five years in New South Wales Australia, correlated improvement in anesthesia outcome with improved

anesthesia training. (Holland 1987) This is among the very few studies which even considers the question of whether better education improves anesthesia-related outcome. Limitations include the fact that it only involved physicians and it did not investigate mechanisms of untoward outcomes, or even categorize them into lack of knowledge versus lapses and vigilance errors.

Few negative anesthesia related outcomes in America are assessed or judged as to cause by responsible and educated individuals or panels of anesthesiologists. The outcomes are often ignored if the patient (now a potential plaintiff) is not judged to "have a case" by lawyers, or is too old to be able to claim sufficient economic loss to interest contingency fee lawyers. Occasionally they are adjudicated by laymen or juries, with decisions often poorly related to what actually occurred in the operating room.

A National Anesthesia Outcome Registry is needed to begin to discover the outcomes of the more than 25 million anesthetics administered each year in the United States. Such a Registry would stimulate, coordinate, and record the results, both good and bad, of <u>every</u> anesthetic administered in a given hospital, because a valid <u>denominator</u> is needed, not just a numerator. It would require ongoing, voluntary, high volume reportage by public and private hospitals alike of anesthesia outcome data, protected from discovery and funded by an unbiased source such as NIH or AHCPR (Agency for Health Care Policy and Research). For example, all perioperative patient deaths would be reported and each investigated by an expert committee of the Registry to determine cause. This would provide legitimate anesthesia-related risk data for death. Other process outcomes, including "critical incidents", would also be included.

Who really performs anesthesia in America? How safely? What are the frequencies and mechanisms of anesthesia-related morbidity and mortality? What about regional vs. general, volatile agents vs. intravenous, and all the many other choices we make today for our patients based on preferences but not data? In order to begin to answer these crucial questions, which are at the very heart of quality improvement in anesthesia, a denominator is needed;

not for Canada, England, New South Wales, or elsewhere, where conditions and practice patterns differ; not from prior years or decades, but in America for the 1990's. Such a National Anesthesia Outcome Registry would enable us to begin to overcome *the first major obstacle* to improving quality in anesthesia in the United States, namely *our lack of information about our real results*. The argument and need for this information is further strengthened by the inherent difficulty we have separating anesthetic processes and outcomes from those of surgery and disease.

What if fully trained, Board certified anesthesiologists are not "better" and/or "safer" after valid severity of illness indexing for particular procedures, and after valid large volume outcome data are available? We believe anesthesiologists will have gained a remarkable opportunity, a powerful impetus to improve and the insight as to where specifically to direct our efforts--exactly what Deming advocated and the Japanese cherish as the premier tool for quality improvement.

Conclusion

The traditional paradigm to optimize quality in health care assesses performance and then determines whether it "conforms" to standards. The pioneers of industrial quality improvement--Shewart, Dodge, Juran, Deming, and others taught that this approach is ultimately unsuccessful. Important quality advances in anesthesiology may depend upon application of principles of modern industrial quality science, principles which demand a new approach to recognition, analysis, and elimination of quality problems accompanied by driving out fear of retribution or punishment when problems are reported. Before this is possible, we believe that a major, coordinated effort is needed, embodied in a National Anesthesia Outcome Registry, to gather data which will make targeting of quality problems possible and provide impetus and focus to improve them. Not to weed out "bad apples" or to provide for ascendancy of one group of anesthesia providers over another, such a Registry would provide our specialty

with a great opportunity, a vehicle to detect "system flaws" in our approaches to educating our trainees and ourselves and practicing our specialty. This application of the Deming philosophy could radically improve our understanding of and priorities for our profession, on a smaller scale but to no less extent than happened in industry in post-war Japan.

Deming's Fourteen Points

1. Create constancy of purpose for improvement of product and service.
2. Adopt the new philosophy.
3. Cease dependence on mass inspection.
4. End the practice of awarding business on price tag alone.
5. Improve constantly and forever the system of production and service.
6. Institute training.
7. Institute leadership.
8. Drive out fear.
9. Break down barriers between staff areas.
10. Eliminate slogans, exhortations, and targets for workforce.
11. Eliminate numerical quotas.
12. Remove barriers to pride of workmanship.
13. Institute a vigorous program of education and retraining.
14. Take action to accomplish the transformation.

Table 1

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