

White Paper for Patient Safety:

In search of the “BLACK BOX”

for a reliable and cost-effective quality control of the delivery of medical care.

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The reason airline transportation is the safest of all transports is due to the famous “black box” that provides the necessary first step, i.e. the accurate “diagnosis.” Without that reliable “forensic” analysis, the “blind lead the blind.”

The reason the Federal Aviation Agency (FAA) is effective is because it has jurisdiction over every aspect of the airline industry, including pilots, mechanics, flight attendants, management and manufacturers. It can prevent disasters because it has the power to act immediately, without the intervention of any other agency, e.g. the U.S. Department of Justice and its lengthy process. The FAA can ground, at once, a particular type of plane or an entire airline company, with good cause. Without it, planes would crash daily.

There is no such equivalent in the healthcare industry, however the taxpayer is spending billions of dollars on multiple layers of county, state, federal and not-for-profit agencies that are defective by design. On November 24, 2002, Dennis O'Leary, M.D., President of JCAHO (Joint Commission on Accreditation of Healthcare Organizations) said, "There are some who believe that this whole system has to be blown up and start over again, I happen to be one of those advocates."¹ In 2004, the GAO (Government Accountability Office) provided its own devastating analysis.²

Is it possible to have a “black box” in the health care industry? Absolutely, yes.

In clinical research, to evaluate new treatments we use randomized “double-blind” studies, where neither the physicians nor the patients know which pill is a placebo and which pill actually contains the drug. We can do the same when evaluating any error or complication in the health care industry, whether it's in the hospital, the doctor's office, the pharmacy, the manufacturer of a medical device, etc.

We have about 900,000 licensed physicians in the US and 100,000 of them are in California. That's a terrific, diversified pool to serve in a "black box."

Whenever any error or complication is reported, it could be submitted anonymously, i.e. without the patient's name, the physician's name, the hospital's name, the city or state, to an odd number (7 to 11) licensed individuals who will also remain anonymous to the patient, physician and hospital. This anonymity will assure an unbiased, impartial

opinion, void of any possible conflict of interest. Such an approach also eliminates any concern of “immunity,” as the identity of those individuals will never be known.

A “black box” method of investigation should combine multiple disciplines, i.e. physicians, pharmacists, nurses, administrators, medical device manufacturers, laboratory technicians, etc., because errors and complications in the health care sector can result from various sources in a hospital, a laboratory, a pharmacy, a doctor’s office, etc. “It’s the system stupid,” as R.M. Wachter, M.D. and K.W. Shojania, M.D. point out in *Internal Bleeding – the truth behind America’s terrifying epidemic of medical mistakes*.³

Such a “black box” could be consulted in lieu of “experts” by state medical boards investigations, hospitals’ peer review, medical malpractice cases, Medicare investigations, etc., since their “experts” are at times the weak link or “Achilles tendon” of the system.

Such a “black box” could also prevent future errors and complications because the opinions of each member of such a “black box” would be reviewed and a physician, a pharmacist, a nurse, or an administrator whose professional opinion may fall below the acceptable standard of practice could be identified and educated in such a proactive “two way” analysis. Isn’t the whole purpose of peer review to learn from our colleagues’ mistakes so that we can reduce errors and complications in our industry by not repeating them.

Such a “black box” participation should be mandatory as a part of maintaining and renewing the licenses’ of physicians, nurses, pharmacists, hospitals, etc., in the same way that participation in peer review is mandatory under the bylaws of hospitals for physicians in order to maintain their “active” status. We could save the taxpayer a lot of money by merging all state boards - medical, nursing, pharmacists, tissue bank, laboratory, hospitals -, into a single state and federal oversight agencies. Thus, their investigative capabilities would be merged into one single comprehensive unit, much like our multiple intelligence agencies are coordinated through the “Homeland Security” Department. This is the only way to achieve a uniform quality control across the country. See articles in the Washington Post by CW Thompson regarding the disparate effectiveness of various state medical boards⁴

Such a multidisciplinary system will easily overcome the multiple deficiencies due to limited “jurisdiction” presently encountered by the existing agencies. Currently, an investigation by a state medical board can find wrongdoing by a hospital, yet cannot act upon such finding because it has no jurisdiction over hospitals.

On the other hand, the DHHS (county, state or federal agencies) cannot act based on a medical state board investigation. It has to proceed with its own investigation that may be limited by its own restrictions of “jurisdiction.”

This “black box” comes very cheap. The physicians could be paid the same as members of a jury in courts where physicians and nurses usually do not serve because the time required to serve on a jury could adversely impact their patients’ care. As a

reward, participation in the “black box” would provide the participants CME credit, with AMA or specialty organizations such as ACOG-cognates. It would pay for itself through the existing licensing fees paid by physicians, nurses, pharmacists, hospitals and taxpayers.

Since Kip Viscusi, an economist at Harvard University, estimates the value of a human life to be worth between 4 to 9 million dollars in the U.S. , every life saved represents a savings of 4 to 9 million dollars to the US economy.⁵

In July 2004, the HealthGrades study, "Patient Safety in American Hospitals,"⁶ demonstrated the devastating effects of errors and complications in the health care industry and established the loss of 600,000 human lives every three years. That represents 2.4 trillion to 5.4 trillion dollars wiped out of the U.S. economy every three years, or 800 billion dollars to 1.8 trillion dollars every year, as 200,000 humans, i.e. taxpayers, consumers, productive people, disappear from our society annually.

In 2002, our national health care cost was \$1.6 trillion (about 15% of the Gross Domestic Product (GDP). If one considers the additional economic impact of health care errors and complications, the total health care cost may actually be about 30% of the United States' GDP. Accordingly, there is no reason for the taxpayer to continue to waste public funds for obsolete and ineffective layers of organizations and agencies that are not capable of fulfilling their mission even if they wanted to.

This was convincingly illustrated by whistleblower Charles Rosen, M.D., who stated in a 7/25/2003 Street.com article that he observed at his hospital a "deliberate attempt at cover-up for financial reasons" and wondered why no agency was intervening after he reported the source of the unusually high infectious rate at his facility.⁷ No wonder patients are afraid of hospitals. See the *Wall Street Journal*, 9/11/2003, article by Laura Landro, "How to keep the Hospital from Making you Sicker."⁸ That's why alternative medicine is so popular.

Once the “black box” is operational, it will markedly reduce the number of litigations by patients and their families, victims of errors and complications, and decrease professional liability premiums. (See Figures 1 and 2, The "Big Picture")

The "black box" could assist justice, as the legal system and courts in general are intimidated by any intervention in the medical field. Judges feel they lack the necessary expertise and thus fear allowing a potentially bad physician to return to medical practice. In the name of “public interest," judges prefer to err against the physician, even when the allegations are clearly silly, and thus assume the presumption of correctness of the process of hospitals' "hearings". Hospital attorneys have for many years very skillfully abused these shortcomings by courts all over the country.

Judges are also mindful not to overburden an already costly health care system. They do not realize that by protecting hospitals' administrators and their boards, the runaway health care costs will never stop growing because errors and complications are a great source of revenues for them. In USA Today, Lucian Leape and his researchers stated on 5/18/2004.⁹ "We have to turn the heat up on the hospitals...." as "...there's no

economic incentive for hospital's to reduce errors because they make more money by treating the resulting problems." See also Professor Leape's *JAMA* article. ¹⁰

So far, federal prosecutors have not been able to compel any significant change in the conduct of the management of hospitals despite several multi-billion dollar settlements by the U.S. Department of Justice vs. NME, HCA, Tenet and others, as these administrators (CEOs, COOs, etc.) continue their devastating practices under their corporate umbrellas, following those settlements.

If we genuinely want America to be competitive and have a healthy workforce, we need to reduce the individual, corporate, insurance and government financial health care burden by establishing, as quickly as possible, a meaningful, credible, cost effective and reliable quality control for the health care industry. We need not forget that as our population's age grows, its health care needs and costs will continue to rise, yet we have some of the finest physicians, nurses, pharmacists, etc. in the world and we have the most advanced technology available to us. Thus, we cannot allow this organized sabotage to persist and undermine the quality of the delivery of medical care in our country.

When Congress passed the HCQIA, it failed to establish a HCQIA- Agency to assure the mission and intent of Congress because it depended on a "licentiates"-driven peer review reinforced by legislatures in Business and Professional Codes of California and other states. Alas, that wishful thinking rarely materialized.

We have to learn from the experience of years of repeated failures. As observed in "Clinical Peer Review or Competitive Hatchet Job" by William W. Parmley, MD,¹¹ too often the physician members of the "old boys network" abuse peer review as a tool to protect each other by covering up acts of negligence or to eliminate their competitors.¹²

Peer review, controlled by hospital administrators' greed and economic interests, has totally failed to achieve the quality control that Congress and California's legislature assigned to it., Hospital administrators are the "gate keepers" who control which medical records are submitted to the peer and chart review committees and which physicians escape scrutiny. Hence, they cover up the wrongdoings of those physicians who represent significant revenues in order to secure their stream of profits. See "Rape of the Medical Peer Review Process By Tenet Healthsystem."¹³ That's what happens in many hospitals. See *Critical Condition – how US healthcare became big business and bad medicine* by Donald L. Bartlett and James B. Steele¹⁴ and the outstanding "Cost of Courage" series in the *Pittsburgh Post-Gazette* by Steve Twedt, a comprehensive investigation of systematic failures of peer-review nationwide, published 10/26/2003 to 10/29/2003. ^{15, 16}

It is said that, "Internists know everything but see nothing, Surgeons see everything but know nothing, and Pathologists know everything and see everything but, too late. " By the time the FBI raided "Redding," they "knew and saw everything, but too late" for the victims and people who died as a consequence of unnecessary and non-indicated cardiovascular surgeries performed at that facility. See "Unhealthy Diagnosis," 60 Minutes, CBS, July 25, 2003. ¹⁷

The matter of quality control in the health care industry cannot be limited to the agenda of a single party, Republican or Democrat. Nor is it a political ideology, i.e. capitalism or socialism. It can only be achieved by taking into consideration humans' natural limitations, e.g. egos, bias, partiality, conflicts of interests (economic or other), discriminatory, arbitrary, capricious or malicious conducts. The "black box" circumvents all of the above human shortcomings. No laws passed by Congress or any legislature can change nature's own biological, sociological, and psychological laws, i.e. the organic human deficiencies.

The Romans proclaimed a long time ago that, "Errare humanum est," i.e. "To err is human" and the famous maxim, "Primum no nocere," i.e. "First do no harm." Isn't it about time for us to implement this wisdom and common sense? How many more human lives will be victims before we establish a true, effective and reliable quality control of the delivery of the medical care in our country?

Don't we say, "Where there is a will, there is a way"? Isn't that the American way?

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Figure 1.

The "Big Picture"

1. No Peer Review or Sham Peer Review

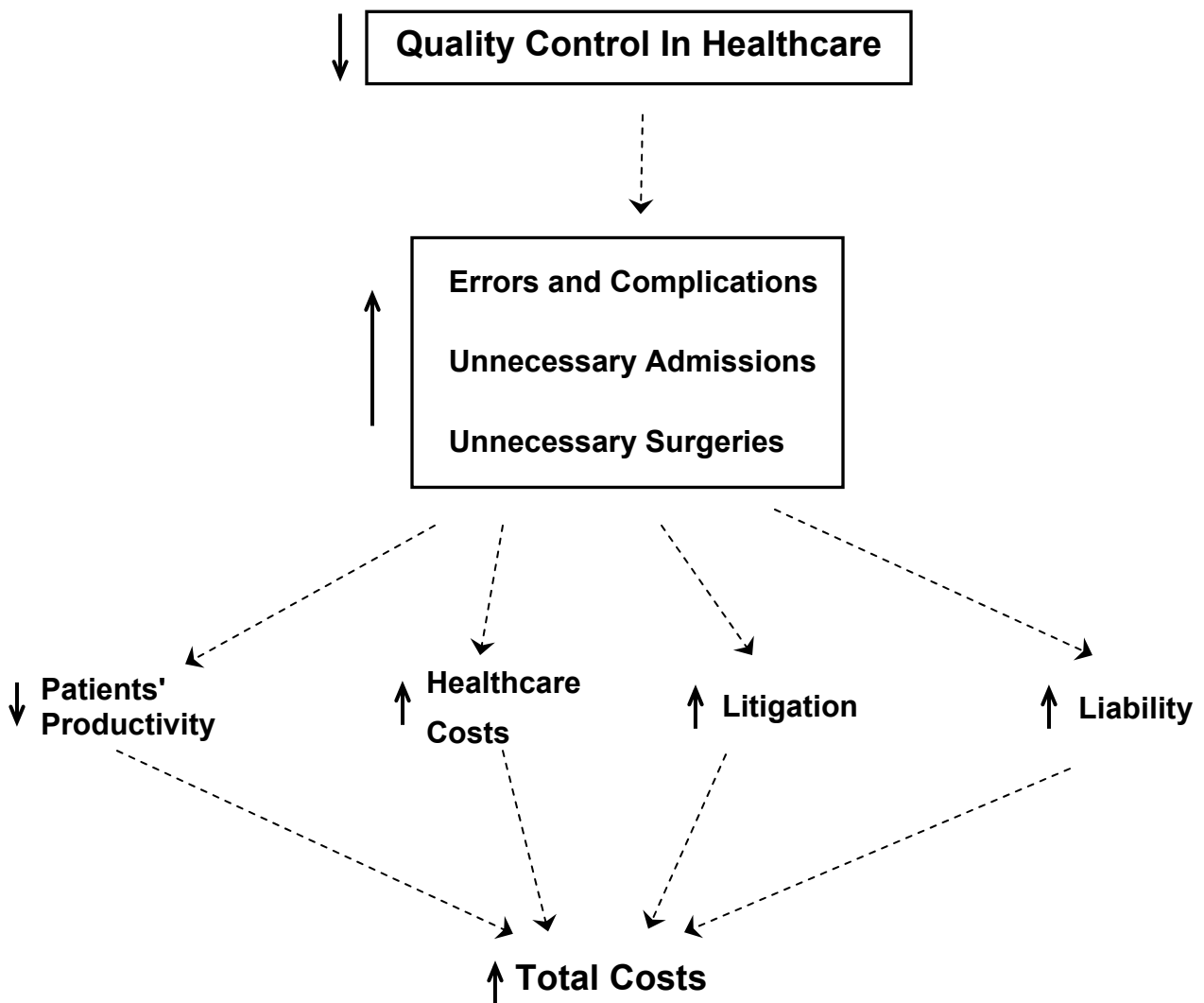


Figure 2.

The "Big Picture"

2. Legitimate Peer Review

