When Hyperbole Masquerades As Patient Safety Advancement

"There are times when a single, unexpected death sparks a change in medical practice." Dr. Hardeep Singh's WSJ Op-Ed The Battle Against Misdiagnosis* (Aug. 8) is a study in contradictions, and is a timely contrast to my latest PRWeb press release* and Open Letter* on my web site that are based upon The Biggest Mistake Doctors Make, Laura Landro, WSJ, Nov. 18, 2013. (* See References)

Dr. Singh illustrates what has always been missing in the efforts to improve patient safety in the first paragraph of his WSJ Op-Ed. "The tragedy prompted New York State* in January 2013 to introduce "Rory's regulations,"* a set of stringent protocols aimed at preventing similar incidents in hospitals."

Dr. Singh's prophetic declaration will hopefully open Pandora's box regarding what has always been missing in every effort to improve the quality of health care and patient safety, i.e., each state's responsibility to create and maintain a functional and effective health care delivery system. Two fundamental facts; all medical care is local*, and states license doctors establish the rationale for New York State's creation of "Rory's Regulations". Yet each state's responsibility to contribute to the efforts to improve patient safety is rarely found in any of the patient safety efforts during the past quarter century.

This well-intended critical review of Dr. Singh's assessment begins with a few excerpts taken from **New York State's Rory's Regulations:**

Hospital Sepsis Protocols (Rory's Regulations) Effective 5/1/13 (31 pages)
New York Commissioner of Health has authority to add, delete, or modify that state's Official Compilation of Codes, Rules and Regulations regarding health care. Thus Rory's Regulations amended and increased existing rules and regulations regarding patient care by adding evidence-based patient care protocols.

405.4 Medical Staff.
(a) Medical staff accountability. The medical staff shall be organized and accountable to the governing body for the quality of medical care provided to all patients. (Dr. Marty Makary's 2012 book Unaccountable describes how well that method of accountability in hospitals has worked)

Statutory Authority:
Public Health Law ("PHL") Section 2800 provides that "[h]ospital and related services including health – related service of the highest quality, efficiently provided and properly utilized at a reasonable cost, are of vital concern to the public health. In order to provide for the protection and promotion of the health of the inhabitants of the state…, the Department of Health shall have the central, comprehensive responsibility for the development and administration of the state's policy with respect to hospital related services…."

PHL Section 2803 authorizes the Public Health and Health Planning Council ("PHHPC") to adopt rules and regulations to implement the purpose and provisions of the PHL Article 28, and to establish minimum standards governing the operation of healthcare facilities. (How well has that system of patient safety worked thus far?)

In New York State the number of **severe** sepsis cases increase from 26,001 in 2005 to 43,608 in 2011 – an increase of 68%. Similarly, the number of sepsis cases in New York State increased from 71,049 in 2005 to 100,073 in 2011, an increase of 41%.

Rural Area Flexibility Analysis
Effect of Rule:
The provisions of these regulations will apply to general hospitals in New York State, including 47 general hospitals located in rural areas of the state. These hospitals will not be affected in any way different from any other hospital.

Question: Can anyone in the New York Commissioner of Health bureaucracy describe in great detail the structure of that state's health care delivery system by naming each component, describing how each component functions, and then illustrate any possible systematic collaborations between components that should take place in any "system"?

States license doctors and all medical care is local!
But Dr. Singh's glowing expectation of "a change in medical practice" uses an all too common patient safety event that has taken place in numerous states during the past several decades, and each were met with similar euphoria. Rory's Regulations is unfortunately a very sad old song now sung to a new melody.

Dr. Singh's Op Ed made reference to the NAS/IOM Diagnostic Error in Health Care* two-day event that took place in Washington DC Aug. 7-8. 2014. The first day's meeting agenda* and list of Committee Membership* are provided. The second day was held in Closed Session. No evidence of each state's responsibility appears in the first day agenda.

Perspective:
Rory's Regulations tells us that New York State has 47 rural hospitals, but Becker's Hospital Review provides a far larger perspective.
100 things to know about healthcare in Texas:*
There are 630 hospitals with 83,000 licensed beds in Texas….
Harris County (Houston) is home to 80 hospitals, Dallas County 42, Tarrant County (Fort Worth) 39, and Bexar County (San Antonio) 32, plus 27% of all hospitals in rural areas.

South Carolina, where I live, has 68 hospitals and 65 surgery centers (but surgery centers are rarely mentioned in patient safety events or literature).

Question: How does Dr. Singh and other SIDM members currently obsessing with the new day of patient safety that Rory's Regulations will create envision the process to be

used to make those positive regulations become reality in all of the hospitals in the nation?

Answer: Sadly, they can't. But during all of the euphoria that is taking place regarding Rory's Regulations there continues to be silence regarding the much larger, and true measure of patient safety in the current health care non-system.

Every new estimate of needless hospital deaths is significantly greater than all previous estimates during the past quarter century!

I am a father and grandfather, and fortunately I have never suffered the loss of a child, therefore my grief for Rory's parents*, and other loved ones is tempered. And I take no pleasure in "raining on their parade", but everyone seeking to improve the quality of health care and patient safety must focus on the facts.

Between Brennan and Leape's* 1990 estimate of 98,000 needless hospital deaths, IOM To Err Is Human* 2000 promise to reduce that number by 50% in five years, and the latest John James* 2013 estimate that is quadruple that original 1990 estimate one should assume the establishment of a track record of abject failure. Particularly when knowing that Dr. Leape, and others strongly supported James' findings the same month of his article being published.

Diagnostic Error in Medicine 7th International Conference, Atlanta, Sept. 14-17, 2014*
Diagnostic error is the leading cause of medical malpractice claims in the US and is estimated to cause 40,000 – 80,000 deaths annually. One in every ten diagnoses is wrong, and one in every thousand ambulatory diagnostic encounters result in harm. The Diagnostic Error in Medicine Conference is focused on **Merging Policy, Practice and Technology: Paths to Improve Diagnosis.**

Dr. Lucian Leape, Father of Patient Safety*, will be the Keynote Speaker on Monday, Sept. 15, 2014.

A Brief History:
Drs. Brennan and Leape began their research in upstate New York hospitals in 1986 that culminated in their 1990 estimate of 98,000 needless hospital deaths annually. Dr. Donald Berwick and two co-authors published Curing Health Care in 1990 and published a revised version in 2002. So the past quarter century of efforts to improve patient safety has at least produced a documented track record, but not the one hoped for.

IOM To Err Is Human was the first book in their Crossing The Quality Chasm series of seven books that were published between 2000 and 2004. I have reviewed six of those seven books and have published a copy of the 53 recommendations offered in those six books. I challenge anyone to pick out five of those 53 recommendations they consider the most promising, and seek to find how they may have contributed to far greater patient safety in any state in the past decade.

Inaugural Johns Hopkins Patient Safety Forum Convenes "Thought Leaders" to Address Challenges Release date: 09/11/2013

Pilot "Sully" Sullenberger and patient safety expert Peter Provost, M.D., to deliver keynote presentations

BACKGROUND: What can health care organizations and clinicians learn from submarine warfare and industries as varied as nuclear power, aerospace, education and hospitality? That's a question the inaugural Forum on Emerging Topics in Patient Safety, presented by the Johns Hopkins Armstrong Institute for Patient Safety and Quality and the World Health Organization, seeks to answer. The three-day event will begin together creative thinkers, scholars, teachers and leaders from health care, government, consumer research and business with the goal of significantly accelerating the pace of improvement and patient safety.

My Note: That event concluded on the third day with all attendees choosing one of three World Cafes seeking to "harness the group's collective wisdom." I was recently told that the Armstrong Institute has NO work product available for dissemination that resulted from those World Cafes and that greatly heralded patient safety event.

Thirteen years after Dr. Leape testified before a U.S. Senate Sub-Committee on how he, and others planned to take safety measures from established industries, i.e., commercial aviation, and impregnate them into the health care delivery system (a large, complex, non-system none of them can first describe in detail) and thereby greatly improve patient safety John James published his Sept. 2013 article, strongly supported by Dr. Leape, demonstrating the sad results of those sincere, but misguided efforts.

Why have those sincere efforts resulted in failure?

The missing two fundamental facts, and resulting conclusion; all medical care is local, and states license doctors; therefore each state is responsible to create, and maintain a functional health care delivery system, with an organizational structure that will allow for clearly defined points of authority, and delegated authority.

Accountability is a by-product of authority, and as Dr. Makary so clearly describes in his book Unaccountable, meaningful accountability can never exist in a non-system. Yet Dr. Singh describes Rory's Regulations as "a set of *stringent protocols* aimed at preventing similar incidents in hospitals." The IOM Quality Chasm exists between Dr. Makary's description of unaccountability, and Dr. Signh's stringent protocols.

As long as patient safety experts continue to try to take safety measures from entities that could never continue to exist without an organizational structure, and all necessary characteristics such an entity must have, and claim they will inject those safety measures into a "system" that has long been recognized to be a non-system the public will continue to be supplied with false promises.

Those offering contrarian thinking have been met with hostile reproach throughout the history of Medicine. The story of Semmelweis is just one of many such episodes of how professionals can too often react in an unprofessional manner.

Semmelweis did not create the fact that if doctors washed their hands, and sterilized their instruments lives could be saved. He recognized, tested, and proved their value. Lister had to save the medical profession of his day from them-selves.

I did not create the facts that all medical care is local, and states license doctors. But quality of care, and patient safety experts will have to incorporate those fundamental facts into all future efforts to make health care safer, or they will continue to replicate their failures of the past.

I can provide a plan for a 21st century health care delivery system that would go far beyond anything previously imagined. But my plan is based upon the recognition that each state is responsible to create and maintain an effective health care delivery system that contains an organizational structure, with clearly defined points of authority, etc. Chaos reigns when fundamental facts continue to be ignored.

As a SIDM member I hope my criticism will be accepted, and responded to, in the manner in which it is offered.

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