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Clinical Integration and Collaborative Care: Enforcement Meets Quality

Council of Deans Regional Fall Meeting

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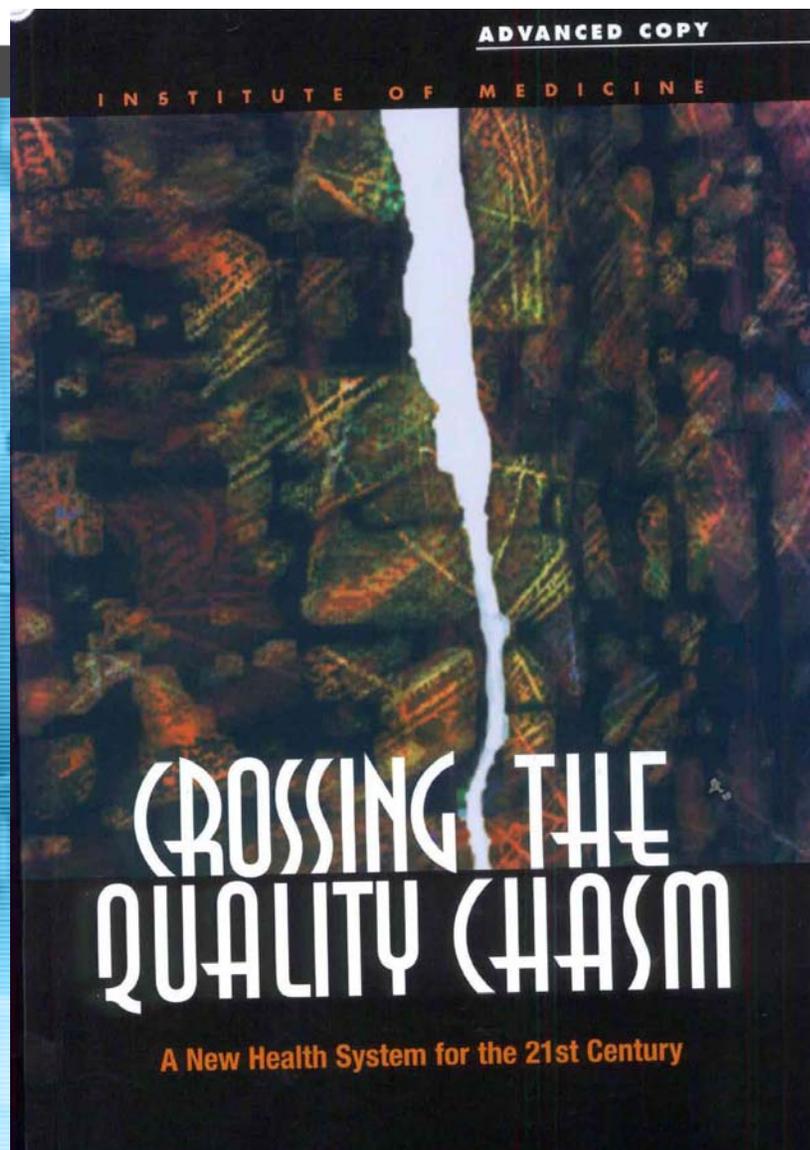


U.S. Healthcare System Realities

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- Mixed public and private system
- Health care is driving the U.S. economy
- Health care system is extraordinarily advanced, yet inefficient, uneven and too often unsafe
- Improvement will require collaboration, integrated care and aligned incentives
- Enforcement priorities are not necessarily aligned with policy needs and operational realities





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“The American health care delivery system is in need of fundamental change. Many patients, doctors, nurses and health care leaders are concerned that the care delivered is not, essentially, the care we should receive ... Quality problems are everywhere affecting many patients. Between the healthcare we have and the care we could have lies not just a gap, but a chasm.”

— Institute of Medicine, 2001



“I don’t want to achieve immortality
through my work . . . I want to achieve it
through not dying.”

— Woody Allen

Results of Commonwealth Fund Scorecard

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- The “National Scorecard on U.S. Health System Performance,” released September 20, 2006, is a comprehensive evaluation of U.S. health care quality, access, equity, outcomes and efficiency
- For 37 key indicators of the five health care system dimensions listed above, overall U.S. score equals 66 out of a possible 100
- Efficiency was the single worst score among the five dimensions. For example, in 2000/2001, U.S. ranked 16th out of 20 countries in use of EHRs
- We are worldwide leader in costs



Commonwealth Fund Scorecard (cont.)

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- U.S. scored 15th out of 19 countries in mortality attributable to health care services
- Basic tools (i.e., Health IT) are missing to track patients through their lives
- We do poorly at transition stages — hospital readmission rates from nursing homes high; our reimbursement system encourages “churning”
- Improving performance in key areas would save 100,000 to 150,000 lives and \$50 billion to \$100 billion annually



Commonwealth Fund Recommendations

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- Expand health insurance coverage
- Implement major quality and safety improvements
- Work toward a more organized delivery system that emphasizes primary and preventive care that is patient-centered
- Increase transparency and reporting on quality and costs
- Reward performance for quality and efficiency
- Expand the use of interoperable information technology
- Encourage collaboration among stakeholders



Rewarding Provider Performance: IOM Pay-for-Performance Recommendations (September 2006)

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- The Secretary of the Department of Health and Human Services (DHHS) should implement pay for performance in Medicare using a phased approach as a stimulus to foster comprehensive and system-wide improvements in the quality of health care
- Congress should create provider-specific pools from a reduction in the base Medicare payments for each class of providers (hospitals, skilled nursing facilities, Medicare Advantage plans, dialysis facilities, home health agencies, and physicians)



IOM Pay-for-Performance Recommendations (cont.)

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- Congress should give the Secretary of DHHS the authority to aggregate the pools for different care settings into one consolidated pool from which all providers would be rewarded when the development of new performance measures allows for shared accountability and more coordinated care across provider settings
- Because public reporting of performance measures should be an integral component of a pay-for-performance program for Medicare, the Secretary of DHHS should offer incentives to providers for the submission of performance data, and ensure that information pertaining to provider performance is transparent and made public in ways that are both meaningful and understandable to consumers



IOM Pay-for-Performance Recommendations (cont.)

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- The Secretary of DHHS should develop and implement a strategy for ensuring that virtually all Medicare providers submit performance measures for public reporting and participate in pay for performance as soon as possible
- Three years after the release of this report, the Secretary of DHHS should determine whether progress toward universal participation is sufficient and whether stronger actions—such as mandating provider participation—are required



IOM Pay-for-Performance Recommendations (cont.)

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- CMS should design the Medicare pay-for-performance program to include components that promote, recognize, and reward improved coordination of care across providers and through entire episodes of illness
- Because electronic health information technology will increase the probability of a successful pay-for-performance program, the Secretary of DHHS should explore a variety of approaches for assisting providers in the implementation of electronic data collection and reporting systems to strengthen the use of consistent performance measures



Quality vs. Cost?

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“Right from the start it has been one of the great illusions in the reign of quality that quality and cost go in opposite directions. There remains very little evidence of that. There may be some innovations that raise costs while raising quality, but many, many improvements reduce costs.”

— Don Berwick
[Health Affairs](#), October 2005



Value-Based Purchasing

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U.S. Department of Health and Human Services
Medicare Hospital Value-Based Purchasing

Options Paper

2nd Public Listening Session
April 12, 2007

Prepared by the CMS Hospital Value-Based Purchasing Workgroup
with Assistance from the RAND Corporation, Brandeis University,
Booz | Allen | Hamilton, and Boston University



Creating Value-Based Competition on Results

- Integrated care is the goal, not aggregation of boxes
- High quality = less cost = value to patients
- P4P must incent lower costs
- Value must be measured, communicated and compensated

Porter and Teisberg Conclusion

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“Value-based competition on results is a positive-sum competition in which all participants can win, so long as they are dedicated and capable. However, those participants that will enjoy the greatest rewards will be those that move early. For anyone in the health care system, the time to act is now.”



Opportunities to Improve Quality and Reduce Costs

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- Pay for Performance
- Gainsharing
- Ambulatory Surgery Centers
- Service Line Joint Ventures
- Medical Group Consolidation
- Management Contracts and Leasing Arrangements
- “Under Arrangements” Arrangements



But Legal Obstacles Remain

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- Stark Law
- Anti-Kickback Statute
- Civil Monetary Penalty Statute
- Medicare Reimbursement
- Exempt Organization Tax Law
- Antitrust Law
- Quality Monitoring and Reporting



Why Clinical Integration Solves Business and Legal Issues

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- The single entity concept
- Quality is enhanced
- Care is more efficient
- The government recognizes all of this both in law and enforcement policy
- For example, the AMC exception to Stark, employee exceptions to Stark and the Anti-Kickback laws, antitrust guidance on clinical integration



The Stark Law

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Physician Self-Referral Law (aka the Stark Law)

42 U.S.C. § 1395nn

*“Although not the only law, clearly the
threshold law to consider!”*

— David E. Matyas
Epstein Becker & Green, P.C.



The Stark Prohibition

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“...*If* a **physician** (or an immediate family member of such physician) has a **financial relationship** with an entity ..., then the physician may not make a referral to the entity for the furnishing of **designated health services** for which payment otherwise may be made” under Medicare (and to some extent Medicaid)



Stark Penalties

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- Strict Liability
- Knowing violation can result in CMP liability of up to \$15,000 per violation plus 3 times claims and/or \$100,000 per circumvention scheme



Stark Cases, Lawsuits and Settlements

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- Potential for Qui Tam Litigation under the Federal False Claims Act and liability under FCA for Stark violation relates to all referrals by the physician to the hospital (plus penalties)
- Examples of Recent Settlements
 - Tenet Healthcare – Investigations of physician recruitment and relocation agreements; one FL hospital settlement for \$22.5M; others pending
 - Metropolitan Hospital – \$6.25M related to various forms of financial relationships with physicians
 - McLeod Regional Medical Center – \$15.9M settlement related to physician practice acquisition
- **BUT NOTE:** US v. Solinger – Whistleblower lawsuit under above theory dismissed because Kentucky hospital and various medical personnel demonstrated that the financial relationships satisfied the AMC exception (457 F. Supp. 2d 743 (D. Ky. 2006))



The Academic Medical Center Exception

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Excluded from the scope of the Stark law are “services provided by an academic medical center (AMC)” as long as a number of requirements are satisfied



I. AMC Consists of:

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- Accredited Medical School or Accredited Medical Hospital and
- 1 or more faculty practice plans and
- 1 or more affiliated hospitals in which:
 - a majority of physicians on medical staff are faculty members and
 - majority of admissions are by faculty members



II. The referring physician must:

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- Bona fide employee (full or substantial part-time) of component of AMC and
- Be licensed to practice medicine in the state and
- Bona fide faculty appointment and
- Provide either substantial academic or clinical teaching services
- **Note:** Safe Harbor: “Substantial” may be evidenced by 20% of professional time or 8 hours per week
- Others based on facts and circumstances



III. Compensation to referring physician:

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1. Set in advance and
2. Not take into account volume or value of referrals or business generated for the AMC and
3. Not exceed fair market value and
4. Not violate the anti-kickback statute



IV. Additional Requirements:

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- All transfers of money must support missions of teaching, indigent care, research or community service and
- Relationship(s) among the components must be set forth in writing and adopted by the applicable governing boards and
- Not take into account volume or value of referrals or business generated by the physicians and
- Moneys paid to physician for research must be for research or teaching and be consistent with terms of research grant



What's Outside the AMC Exception?

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- Arrangements between the faculty practice plan and unaffiliated hospitals
- Arrangements between faculty practice plan and an affiliated hospitals that does not satisfy the criteria for medical staff and admissions
- Arrangements that include physicians with no affiliation with the faculty practice plan (e.g., 100% private practitioners)
- Arrangements that include physicians who may be affiliated with the faculty practice plan but either are not employed by the University or do not satisfy the substantial time requirements



AMC Exception vs. Other Stark Exceptions

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- If an arrangement satisfies the AMC exception, it does not have to meet another exception under Stark
- Conversely, even if an arrangement does not satisfy the AMC exception, it could still be permitted pursuant to another Stark exception



Examples of Additional Exceptions

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- Employment
- Personal Services Arrangements
- Space and Equipment Rental
- Recruitment



Recent Stark Developments

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- Will there be a Stark III?
 - HR 3162 (Children's Health and Medicare Protection Act of 2007) currently only addresses physician ownership in hospitals
- July 12, 2007 – *proposed* modifications to Medicare Physician Fee Schedule included changes to Stark
 - No modifications to AMC exception
 - Proposed modifications to “Per Click” and Percentage Based Payments
 - Modifications to “Under Arrangements”
 - New “Stand In the Shoes” Concept for Indirect Financial Relationships



Recent Stark Developments (cont.)

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- September 5, 2007 – Stark II Phase III Final Regulations
 - Modifications to AMC exception
 - “Clarifies” that total compensation from each AMC component must be set in advance and not determined in a manner that takes into account volume or value of referrals
 - “Clarifies” calculation in determining if affiliated hospital qualifies under AMC exception based on calculating whether majority of medical staff have faculty appointments
 - Other modifications include, but are not limited to:
 - Recruitment and Retention Exceptions
 - Qualifying as a Group Practice with discussion in preamble about faculty practice plans and foundation models



Stark Is Not The Only Applicable Law

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- Although the Stark Law's AMC exception is a broad exception, it only applies to Stark; other laws must also be considered:
 - The Federal Anti-Kickback Statute
 - Civil Money Penalty for "Gainsharing" and Physician Incentive Plans
 - Medicare Reimbursement
 - Additional Considerations (e.g., tax exempt organization laws, antitrust)
 - Quality Monitoring and Reporting



Federal Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

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- Prohibits the offering, paying, soliciting or receiving any remuneration in return for
 - business for which payment may be made under a federal health care program; or
 - inducing purchases, leases, orders or arranging for any good or service or item paid for by a federal health care program
- Remuneration includes kickbacks, bribes and rebates, cash or in kind, direct or indirect



Penalties

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- Criminal and Civil Penalties
- \$25,000 per offense
- Imprisonment up to 5 years
- Civil Money Penalties (exclusion and \$50,000)



Example of Anti-Kickback Enforcement Environment: University of Medicine and Dentistry of New Jersey

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- 12/05 – UMDNJ agreed to appointment of Federal Monitor as part of Deferred Prosecution Agreement
- 11/06 – Federal Monitor reports potential fraud liability at more than \$80M related to allegations of improper payments to physicians



Anti-Kickback Guidance

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- Statutory exceptions (limited)
- “Safe Harbors”
- Case Law
- Advisory Opinions
- Special Alerts



Personal Services Safe Harbor

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- Written and signed agreement for a term of at least one year
- Aggregate payment amount as well as the services covered must be specified
- If not full-time services, agreement must specify schedule of intervals
- Compensation must be based on FMV and not vary based upon referrals or business



Employment Arrangements

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- Statutory Exception: protects payments by an employer to an employee for bona fide employment in the provision of covered items and services
- Safe Harbor: protects any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program



OIG AMC Advisory Opinions

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- Advisory Opinion 00-6 addressed the donation of a portion of ownership in a medical office building to an agency of the state for use by a medical school
- Arrangement does not result in significant risks to government health care programs because:
 - The transaction is between components of an academic medical center that historically have shared the common mission of training physicians and providing quality medical care to the people of the state and a common heritage as a public institutions
 - The entity certified that it would take steps to insulate physician judgment and income from the pressure to make referrals
 - The proposed donation confers a community benefit on the residents of the city and state



OIG AMC Advisory Opinions (cont.)

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- Advisory Opinion 02-11 involved a state chartered hospital authority, which owns and operates a large teaching hospital affiliated with a state university, making a contribution to an endowment fund affiliated with the University to support research at the University's school of medicine
- The OIG would not impose penalties because:
 - Grant would be between components of an AMC that historically shared a common mission in training physicians and providing quality medical care
 - Grant would be consistent with state legislation establishing the hospital authority to support the education, research and public services of the AMC
 - Considered certifications made by the University to insulate physician judgment and income from pressure to refer to the hospital



Civil Monetary Penalty (42 U.S.C. § 1320a-7a(b))

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- Prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals [entitled to Medicare or Medicaid benefits] . . . under the direct care of the physician
- Penalties of up to \$2,000 per patient covered by the payments



OIG Guidance on CMPs: July 1999 OIG “Gainsharing Bulletin”

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- Stated that the CMP statute prohibits any payment arrangement between a hospital and physicians that is intended to induce a reduction or limitation in services
- Defines “gainsharing” as arrangements in which the hospital gives physicians a percentage of any reduction in the hospital’s costs for patient care attributable in part to the physicians’ efforts



July 1999 OIG “Gainsharing Bulletin” (cont.)

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- Any hospital incentive plan that “encourages” physicians through payments to reduce or limit clinical services directly or indirectly violates the statute
- Such payment need not be “tied to an actual diminution in care” so long as the hospital knows that the payment “may influence” the physician to reduce or limit services to his or her Medicare or Medicaid patients
- No requirement that the prohibited payment be “tied” to a specific patient or to a reduction in medically necessary care



Advisory Opinion 01-01

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- Proposed arrangement in which a hospital would share with a group of cardiac surgeons a percentage of the hospital's cost savings. The OIG approved in light of mitigating factors



Advisory Opinions 05-01 - 05-06

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- In all of these advisory opinions, a hospital proposed to share with one or more groups of cardiac surgeons 50% of the hospital's cost savings arising from the surgeons' implementation of various cost reduction measures
- The OIG found that the proposals implicated the gainsharing provisions but the OIG declined to impose sanctions due to the safeguards established by the parties (similar to previous slide)



Robert Wood Johnson Univ. Hosp. v. Thompson (April 15, 2004)

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- Unpublished New Jersey Federal Court Decision
- Halted a demonstration project developed by CMS and awarded to the New Jersey Hospital Association (“NJHA”) that involved a potential gainsharing arrangement between hospitals and physicians
- Under federal law, the Secretary of HHS is authorized to establish “demonstration projects” to “determine whether . . . changes in methods of payment or reimbursement . . . for health care services under health care programs [such as Medicare] . . . would have the effect of increasing the efficiency and economy of health services without adversely affecting the quality of such services”
- **NOTE:** Deficit Reduction Act of 2005 included a new demonstration project and for purposes of the project exempted these arrangements from the purview of the CMP provision



Other Relevant Legal Considerations

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- Medicare Reimbursement
- Exempt Organization Tax Laws
- Antitrust Laws
- Quality Monitoring and Reporting



Enforcement Meets Quality

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- Innovative hospital-physician financial relationships, including a variety of formal and informal partnering arrangements, are critical to the achievement of all six of the aims set forth in Crossing the Quality Chasm
- Purchasers (public and private) cannot afford overuse, underuse or misuse; patients are harmed by overuse, underuse and misuse



Enforcement Meets Quality (cont.)

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- Evidence based medicine reasonably can define proper use and increasingly so
- The IOM, along with many other organizations and individuals, public and private, working to advance health care quality, have called for the introduction of incentives to induce improved quality, including improved efficiency
- The OIG has called upon health care organization boards to acknowledge quality as a core fiduciary responsibility
- Government should incent proper use and manage regulatory pronouncements and enforcement activities so that they do not disincent proper use



Enforcement Meets Quality (cont.)

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- Current laws and enforcement priorities — Stark law, anti-kickback statute, CMP statute, tax laws — too often disincent innovation and particularly disincent cost efficiencies



Enforcement Meets Quality (cont.)

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- The private sector must continue to educate Congress and the regulatory agencies on the importance of efficiency as a component of quality; the private sector also at times will have to initiate change before the payment system and regulations catch up; but the rewards are potentially very high — in terms of financial and organizational success as well as social benefit
- There is an opportunity for the best performers in the industry to create profound change — and then open up these best practices through transparency of data, and promote collaboration to spread change



“In theory there is no difference between theory and practice. In practice there is.”

— Yogi Berra