

Tenet's CIA: Takeaways for Compliance Program Effectiveness

HCCA Compliance Institute

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Agenda

- I. The CCO's Perspective – Audrey Andrews
- II. Clinical Quality IRO – Neil Smithline, MD FACP
- III. Keys to a Successful IRO Engagement – Tim Renjilian
- IV. Compliance Program Effectiveness Review/Board Advisor –
David Yarin

Chief Compliance Officer

Audrey Andrews

Top Ten CIA Lessons Learned

- On day 1, define what success looks like at the end of the term
- Use a values-based program--not a CIA-based program
- Run compliance like an operating unit
- Challenge traditional thinking on policies and training
- Invest in your conflict resolution skills
- What would you want to know if you were the monitor
- Fix the system not the issue
- “Red” is good
- Develop a method for making and sustaining real change
- Be more transparent than you think you need to be

Clinical Quality IRO

Neil Smithline, MD FACP

Assumptions—Clinical Quality

- Health system
- Less than desired performance
- Sincere desire to improve
- Compliance drives quality
 - But, it's not just about policies and procedures

Share lessons learned from a decade of helping multiple health systems improve quality and safety

What It Takes to Drive Quality to New Heights—The Top FOUR

1. Shared vision and goals
2. Leadership at all levels
3. Mutual collaboration and accountability
4. Management by data


Four attributes linking people, strategy & operations to drive best results


	Aggregator	Quality Driven
1. Shared Vision & Goals	<ul style="list-style-type: none">▪ Hospitals set own values and goals▪ Maintain accreditation	<ul style="list-style-type: none">▪ System-wide values, goals, and processes with prescriptive safety culture▪ Hospitals highly aligned with corporate vision and goals
2. Leadership at All Levels	<ul style="list-style-type: none">▪ Accountability primarily financial▪ No explicit expectations beyond TJC and CMS requirements	<ul style="list-style-type: none">▪ Principles of “Just Culture” and transparency drive quality agenda▪ Strong leaders who share values and goals—if not, replaced▪ CEO calls 6 AM meeting with surgeons; stated wrong site surgery is unacceptable – to never happen again

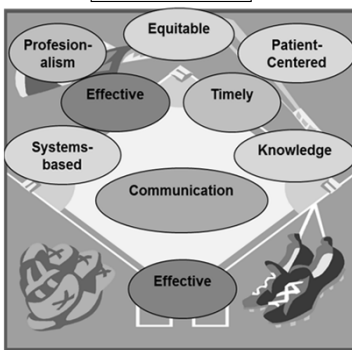
Four attributes linking people, strategy & operations to drive best results

	Aggregator	Quality Driven
<p>3. Collaboration Mutual Accountability</p>	<ul style="list-style-type: none"> ▪ Corporate fostered semi-autonomous hospitals that set own values and goals ▪ Potential causes of patient harm not forthrightly addressed 	<ul style="list-style-type: none"> ▪ “Just Culture” and transparency drive quality agenda ▪ Senior leaders immediately aware of serious patient events—respond decisively ▪ Nurses “stop the line”; more collaborative care team; physicians engaged
<p>4. Data to Focus on Results</p>	<ul style="list-style-type: none"> ▪ Primarily financial ▪ Primarily to meet regulatory requirements 	<ul style="list-style-type: none"> ▪ Rigorous analysis of quality/safety results across organization; investment in IT and staff ▪ Robust collection of clinical quality/safety data, as required by health system

THE PATIENT SAFETY CONFERENCE: A CATALYST FOR CULTURE CHANGE
 St. Christopher's Hospital for Children / Drexel University College of Medicine; Philadelphia, PA



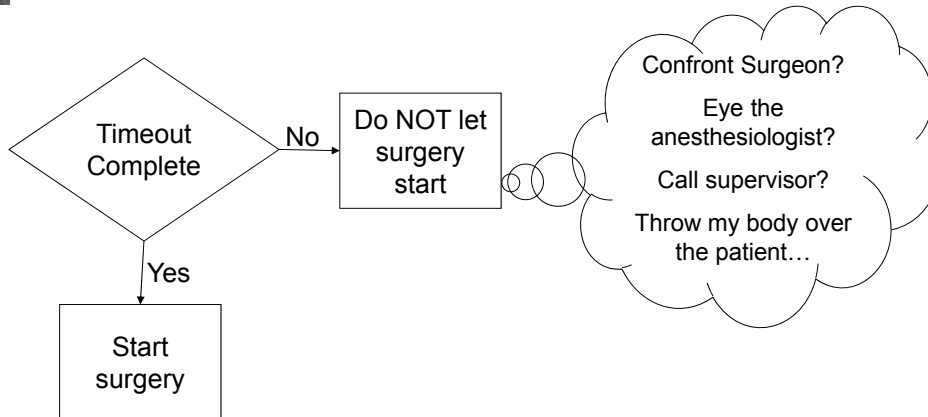


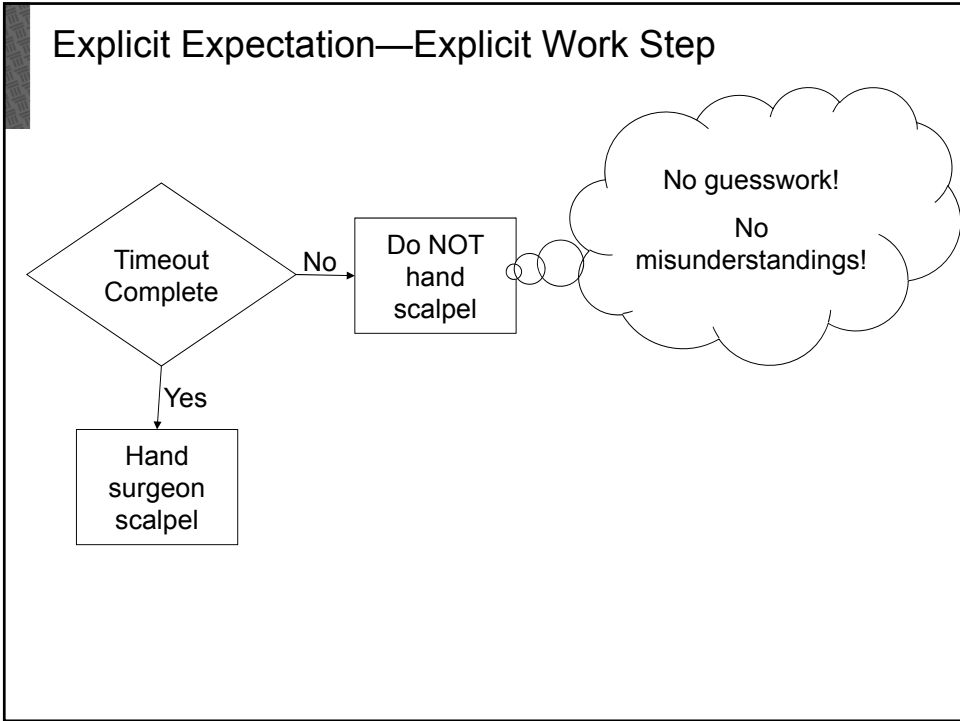
BACKGROUND	SEATING CHART	IMPACT
<p>Traditional M&M</p> <ul style="list-style-type: none"> • “Shame/blame” focus on individuals, not systems • Poor attendance • No change 		<p>Attendance/Participation</p> <ul style="list-style-type: none"> • Attendance ↑ to 200 from 20 • Improved case selection: now all personnel offer potential cases and systems for focus • Newsletter to all staff • Obtained CME credit/GME required attendance
<p>IOM Aims</p> <ul style="list-style-type: none"> • Timely • Effective • Efficient • Equitable • Patient-Centered 	<p>ACGME Competencies</p> <ul style="list-style-type: none"> • Medical Knowledge • Communication • Professionalism • Systems-Based Practice 	

How Do You Know You're On The Right Road

- Being an "Aggregator of Assets" is not enough
- Creative Experimentation
- System drives quality just as it drives growth and reputation
 - What's on your balanced scorecard?
- Explicit expectations at every step
 - What are explicit expectations?

Explicit Expectation—Non-explicit Work Steps





Keys to a Successful IRO Engagement

Tim Renjilian

Keys to a successful IRO engagement

1. Select the right IRO team
2. Get involved with the CIA as early as possible, and carefully review to identify issues or ambiguities that may require discussion with the company or with OIG
3. Consider submitting work plan to OIG for review and comment
4. As other areas of interpretation or judgment arise, err on the side of over-disclosure rather than under-disclosure
5. Develop appropriate communication protocols with the company
6. Consider a visit with the company after the implementation report but well in advance of the end of the Reporting Year
7. Consider performing a "dry run" of any data acquisition routines
8. Define how "balls and strikes" will be called before the work goes live
9. In the IRO report, make sure to put appropriate context around any findings
10. Be consistently mindful of independence

1. Selecting the Right IRO Team

- Knowledge of the IRO process
- Subject matter expertise
- The necessary technical skills
- The ability to scale up if need be
- Scheduling availability

2. Early Review of the CIA

- Language may be overly broad or impractical

- Common issues involve:
 - Timing
 - Scope
 - Inconsistencies
 - Definition of the population
 - Definition of an error

3. Early Work Plan Submission

- Not usually required by the CIA
- OIG will not formally “bless” it, but will provide input on areas of concern
- Helps to avoid problems at the back-end
- Creates an early opportunity to build rapport

4. “Over-Disclosure”

- Some issues require the IRO to exercise judgment or to choose a particular interpretation
- Be mindful of the overall objectives of the CIA and of the CIA’s language
- Provide logic and rationale for key decisions

5. Communication Protocols

- Need to identify key stakeholders in the various processes
- Need to decide when/how potential issues will be raised
- Need to decide when/how potential issues will be dealt with
- Consider communication with board and management on an ongoing basis

6. Early Site Visit

- After the Implementation Report (so that routines have had time to be developed and implemented)
- Before year-end (so changes are still possible)
- Focus on things that might facilitate a more efficient IRO review

7. Data Acquisition “Dry Run”

- Obtaining data can often be more difficult than expected
- Reconciling/validating data can also be challenging
- Don't wait until year-end; develop and test approaches early on while there's still time to tweak

8. Calling Balls and Strikes

- Consider all possible forms of exception based on the language of the CIA and related policies
- Determine what will constitute a reportable exception
- Ensure management buy-in
- Set reasonable expectations

9. Reporting Findings

- Don't simply report what's wrong
 - Provide information on underlying causes
 - Provide information on severity
 - Provide information on trending
- Explain whether the company had already identified the issue, and/or what actions have already been taken

10. Independence

- Most important aspect of the IRO engagement
- Independent of the company, but also of OIG
- Know the relevant independence guidance
- Have established routines for the ongoing monitoring of independence
- Identify and address issues as early as possible

Compliance Program Effectiveness Review/Board Advisor Role

David Yarin

Compliance Program Effectiveness Review/Board Advisor Role

1. In Year 1, gain a detailed understanding of how the compliance program and related activities worked – the who, what, where, when..and update as needed in each successive year
2. Wanted to not only hear about these activities, but see that they were well documented
3. See measurable results, both in compliance program activities and in response to improvement opportunities (i.e. measurable improvement)
4. Perform testing activities that could provide some of the data we were looking for in #3 above
5. See appropriate follow-up or responses to our recommendations for improvement
6. Understand IRO work steps, findings, recommendations and Tenet responses
7. Understand the trends, themes in reportable events and Tenet corrective actions
8. Effective reporting to the Board
9. Regular communication with the CCO, Board sub-committee chair – real-time updates on findings/recommendations throughout the review year
10. Stay current on investigations, significant matters
11. Modify the review workplan and focus areas annually to respond to emerging industry risk areas, internal developments, OIG feedback...

Detailed understanding of how the compliance program worked

- Interviews with key personnel
- Documentation and information review
- Organized around the seven (7) elements and key risk areas

Documentation of compliance program

- Policies and procedures
- Documentation of hotline calls, compliance reports and related investigations
- Documentation of internal audits, findings, recommendations and management corrective actions
- Training and education materials, on-line programs

Measurable results

- Error rates for coding, focus arrangement, quality reviews – trending of
- Employee survey
- Understanding of compliance program – how to report a concern or question, who the chief compliance officer is, retention and understanding of key concepts from training

Testing activities

- Review of hotline case/compliance report sample
- Selected coding areas (e.g. not covered by IRO)
- Sample of internal audit reviews
- Employee compliance survey

Follow-up or responses to recommendations

- Appropriately address the finding
- Reasonable timeframe for implementation and completion
- Follow-up on prior year responses

Understand IRO work steps, findings, recommendations and Tenet responses

- Formed part of the basis for the Board resolution
- Didn't duplicate or overlap with IRO work steps
- Understand the key findings, recommendations and themes identified
- Confirm Tenet responses to recommendations

Understand reportable events and corrective action

- Confirm personnel and systems to identify and report events on a timely basis
- Identify trends in reportable events (e.g. common sources or activities) and corrective action steps

Effective reporting to Board

- Accuracy, clarity and timeliness of reporting
- Avoid general statements; provide objective data
- Provide the story and results of analysis
- Succinct (as one Committee member liked to say – “Give me the last chapter first”)
- Management’s implemented or proposed corrective action to matters discussed
- Meet, but do not exceed the fiduciary responsibility of the Board (i.e. the Board should not be put into a management role)

Regular communication with the CCO, Board sub-committee chair

- Real-time updates
- “No surprises” rule – majority of communication with Directors and Management occurred prior to the Board meetings
- Organized report by 7 elements and/or review areas
- Consistent reporting format
- Executive summary

Stay current on investigations, significant matters

- Again, the “no surprises” rule
- Tenet CCO effective implementation of a “Heat Map” reporting tool

Modify the review workplan and focus areas annually to respond to emerging industry risk areas, internal developments, OIG feedback

- Our organizations and industry risk areas are changing; so was our workplan
- Discontinue certain testing activities if improvement confirmed
- Employee compliance surveys in 3 of the 5 years

Bio/Profile

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Audrey Andrews, senior vice president and chief compliance officer of Tenet Healthcare Corporation, oversees the company's ethics and compliance program and was responsible for the implementation of Tenet's Corporate Integrity Agreement. Andrews reports directly to the Quality, Compliance and Ethics committee of Tenet's Board of Directors. Prior to her appointment as chief compliance officer in 2006, Andrews served as vice president and assistant general counsel for Tenet's regulatory affairs. In that position, she led the law department regulatory group handling Medicare reimbursement, quality of care, and other regulatory issues. She was promoted to senior vice president in 2008. Andrews joined Tenet in 1998 as hospital operations counsel. She joined the compliance section of the law department a year later and began providing legal advice on Medicare reimbursement issues, quality of care, and other specialty areas such as EMTALA and HIPAA. She earned both her bachelor's degree in government and a juris doctorate from the University of Texas at Austin. Andrews is a member of the Health Care Compliance Association, the Health Care Compliance Association, the American and Texas Bar Associations and the American Health Lawyers Association. She serves on the Law and Operational Policy Committee and the Quality Committee of the Federation of American Hospitals.

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Tim Renjilian has been providing compliance consulting, forensic accounting and dispute advisory services to attorneys and corporate clients since 1987. He has extensive experience in health care, government contracting, construction, intellectual property and other matters.

In his dispute advisory role, Mr. Renjilian has developed settlement strategies, performed early case assessments, and analyzed damage calculations. In a nondispute context, he has assisted companies in investigating internal compliance matters and in developing ways to enhance the effectiveness of compliance programs. He has also audited the financial statements of public and private companies with complex accounting and financial reporting systems.

Within the health care a life sciences industry, Mr. Renjilian has helped clients address qui tam lawsuits, congressional and regulatory inquiries, criminal false claims allegations, compliance investigations and other matters. These matters have involved cost report false claims, Anti-Kickback Statute and Stark law violations, outlier payments, medical necessity concerns, coding disputes, and other issues. He has also served as an expert witness in a variety of forums, and has performed a wide range of proactive compliance consulting engagements. He has also performed compliance-related due diligence in connection with the proposed acquisition of health care and life sciences companies.

Mr. Renjilian's clients include the largest for-profit hospital systems in the country; one of the largest non-profit hospital chains; several of the most prominent academic medical centers; leading providers of inpatient rehabilitation, skilled nursing, and home health services; major suppliers of durable medical equipment; and a number of international pharmaceutical and medical device companies.

Prior to joining FTI in 2003, Mr. Renjilian was a partner in KPMG's Dispute Advisory Services practice.

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Bio/Profile

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Dr. Neil Smithline is director of clinical quality for Mercer's National Medical Audit division. In this position, he is responsible for overseeing the clinical standards associated with clinical performance management engagements. Dr. Smithline has more than 35 years' experience in the medical community, including academic positions at the University of Arizona, College of Medicine and San Francisco General Hospital, UCSF. Over his career, Dr. Smithline has served as chairman of the internal medicine department, the intensive care unit, and the department of nephrology at the Tucson Medical Center and at El Dorado Hospital (Tucson). Most recently, Dr. Smithline has served several medical facilities as the medical consultant for clinical resource management, overseeing the quality and appropriateness of care provided. Dr. Smithline's focus has been clinical resource management, evidence-based approaches to health care and medication management, patient risk management and medical cost reduction for hospitals, physicians, employers and insurance carriers. He has also participated in disaster preparedness activities at both the hospital, health system and community level. Dr. Smithline has made numerous presentations, authored more than 70 abstracts and articles, and served as editor-in-chief and publisher of both the Physicians' DRG newsletter and Managed Care Advisor. He is presently a member of the American Society of Nephrology, the International Society of Nephrology, the American Medical Association, and the Healthcare Information and Management Systems Society (HIMSS). Dr. Smithline is board certified in both internal medicine and nephrology, and he is licensed in California and Arizona. He received his BA from Tufts College of Liberal Arts and his MD from Tufts University School of Medicine.

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David Yarin is a managing director in the FTI Consulting Forensic and Litigation Consulting practice and is based in Boston. Mr. Yarin is a member of the Regulated Industries group. He brings more than 20 years of healthcare industry, consulting and project management experience. He has significant experience in leading and managing regulatory compliance, due diligence, litigation support, board advisory, operational and financial consulting projects for healthcare provider, payer and life sciences organizations. Mr. Yarin has served as an independent advisor to the Board of Directors for both a for-profit national hospital system and international pharmaceutical manufacturer, pursuant to corporate integrity agreements. In addition, Mr. Yarin has served as an interim chief compliance officer for an integrated health system/academic medical center. Prior to joining FTI Consulting, Mr. Yarin was a director in another consulting firm, and previously a senior manager in the National Healthcare Regulatory Practice of Deloitte & Touche. Prior to his consulting career, Mr. Yarin worked as a physician group practice administrator for multi-specialty groups based in academic medical centers, including Brigham and Women's Hospital in Boston, Massachusetts. Mr. Yarin has spoken and published on numerous occasions on regulatory compliance, including "Staying on Top of Increased Compliance Scrutiny" at the March 2010 Outstanding Directors Exchange (ODX) conference; multiple Healthcare Compliance Association (HCCA) national and regional meetings, "The Board of Directors' Role in Overseeing Compliance Program Effectiveness" in HCCA's *Compliance Today's* Feature Focus Article for October 2009, and "Detecting and Preventing Drug Theft" in *Hospitals & Health Networks* March 2006 publication. Mr. Yarin earned his B.B.A from the University of Massachusetts at Amherst, and his M.B.A. with a healthcare concentration from Clark University in Worcester, MA.

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