Lab Quality Confab on Quality Management & Diagnostic Medicine

Dr. Allie Karshenas
VP of Sales & Consulting Services East

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REDUCING ... HEALTHCARE QUALITY.

Helping Hospitals/Healthcare Systems Jump Start the Use of Lab Testing to Boost Patient Outcomes

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- Outline of Change Impacting Healthcare
- Competitive Forces Ensuring Change
- The Principles of Six-Sigma
- What is Lean?
- The Basic Fundamentals of 5S & Kaizen
- Tools in Lean Applications
- Quality Traps Used in Clinical Lab
- Healthcare Convergence

Lab Quality Confab on Quality Management in Diagnostic Medicine

The Perfect Storm
Declining Reimbursement • Rising Expenses •
Proliferation of New Technology • Demand

A Grim Picture

- Worst global financial crisis since the Great Depression

- Worst G7 recession since 1930s

- Longest US recession in post-war period – and probably deepest

The Economist

Our guide to America's election
Europe's Schadenfreude
Music on your phone
Reassessing China
Somalia's pirates

World on the edge

The Road Ahead for 2009

With the country facing the worst financial crisis since the Great Depression, Obama has wide latitude to incur fiscal deficits to stimulate economy.

- *Workforce and Education: Both the transition of laid-off workers into new positions, as well as the development of a green workforce, will require investment in education.*

- *New & GreenTechnology and Jobs: Renewable generating capacity will double over three years, transforming the nation's grid and energy workforce.*

- *Infrastructure: The plan enacts the largest infrastructure investment since the creation of the national highway system in the 1950s.*

Chronic Disease
The Burden of Chronic Disease- The Human Burden

People with Chronic Conditions Account for 83 Percent of All Health Care Spending

Health Care Spending for People without Chronic Conditions

17%

83%

Health Care Spending for People with Chronic Conditions

Resource: The Silver Book: Chronic Disease and Medical Innovation in an Aging Nation

Partnership for Solutions 2004, Chronic Conditions: Making the case for ongoing care

Chronic Disease
The Burden of Chronic Disease- The Human Burden

More than Three-Fifths of Health Care Spending is on Behalf of People with Multiple Chronic Conditions

5+ Chronic Conditions
16%

4 Chronic Conditions
12%

0 Chronic Conditions
17%

3 Chronic Conditions
16%

1 Chronic Condition
21%

Percent of Health Care Total Spending by Number of Chronic Conditions

2 Chronic Conditions
18%

Resource: The Silver Book: Chronic Disease and Medical Innovation in an Aging Nation

Partnership for Solutions 2004, Chronic Conditions: Making the case for ongoing care

Rising Costs: Unsustainable for All
Projected Spending on Health Care as a Percentage of Gross Domestic Product

The Problem: More Care is NOT Better Care

US: 10th in life expectancy; 27th in infant mortality

$700 Billion Overspending: Regional variations in quality and cost

Avoidable harm: 99,000 deaths in hospitals from health care acquired infection
Overuse: 13 million unneeded antibiotic RX

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The 4 Ps

The 4 Ps:

Deployment – Improving Access, Quality and **P**roductivity

Mid term research – **P**reventive & **P**ersonalized medicine

Long term research – **P**redictive medicine

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The hospital as center of care

Acute Event

Chronic Disease

Diagnosis → Treatment

Care is now decentralized and fragmented

The future will demand more integration and coordination

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Predictive & Disease Management MEDICINE

↓

INNOVATIVE MEDICINES

↓

PATIENT-TARGETED THERAPIES

Right Medicine

Right Patient

Right Disease

Right Time

Right Dose

Right Response

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Enablers of Preventive and Predictive Medicine

-- Today --

-- Tomorrow --

Diagnosis

Treatment

Prediction

Prevention

Drivers
- *Payer pressures (governments/insurance firms): more prevention, more effective cures*
- *Regulator pressure to try to eliminate adverse events*
- *Demand for better healthcare from the patient*
- *Demand for more accurate healthcare predictions for the patient*
- *Shareholder expectation of growth - getting better medicines to the market faster*

Enablers
- *Development of Genetics and Functional Genomics knowledge*
- *New technologies (e.g. genechips, bioinformatics, molecular diagnostics, etc.)*
- *New regulation on Intellectual Property Rights, genomic ethics, data protection & consent*

Potential areas of interest

Genetics

Diagnostics

Molecular Diagnostics

Gene Therapy

Predisposition Profiling

In Vitro Diagnostics

Imaging

Monitoring Devices

Health Outcomes

Population Stratification

Non-Therapeutic Intervention

Vaccines

Proteins

Therapeutic Intervention

Compliance

Small Molecules

Pharmacoeconomics

Therapeutics

Disease Management

The Powers of Six Sigma- It is about Speed

The 5% Rule
The actual time required to produce a product or deliver a service is only 5% of the total elapsed time.

The 25-2-20 Rule
Every 25% reduction In elapsed time will double productivity and reduce costs by 20%

The 3X2 Rule
Companies that routinely reduce the elapsed time to deliver enjoy growth rates three times the average with twice the profit margins.

Sources of Variation

$$Y = f(X_1, X_2, X_3, \ldots)$$

The Villain

Cost of Poorly Performing Processes (CP³)

Cost of Poorly Performing Processes

σ level	DPMO	CP³
2	308,537	Not Applicable
3	66,807	25%-40% of sales
4	6,210	15%-25% of sales
5	233	5%-15% of sales
6	3.4	< 1% of sales

Each sigma shift provides a 10% net income improvement

Sigma (σ) is a measure of "perfection" relating to process performance capability … the "bigger the better."
A process operating at a "Six Sigma" level produces only
3.4 defects per million opportunities (DPMO) for a defect. Without dedication of significant and appropriate attention to a process, most processes in leading U.S. companies operate at a level between 3 and 4 sigma.

Why is Six Sigma Important?

The Hero

What Does Six Sigma Tell Us?
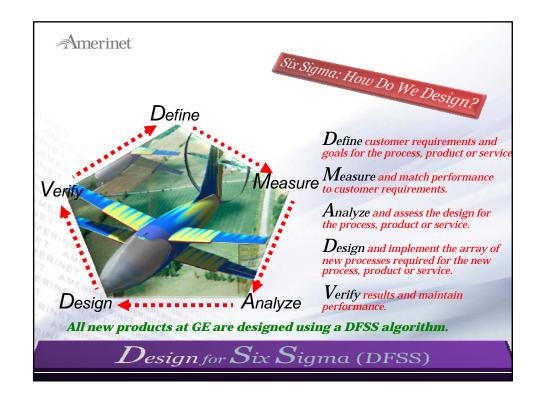
- We don't know what we don't know.
- We can't do what we don't know.
- We won't know until we measure.
- We don't measure what we don't value.
- We don't value what we don't measure.

- *Typical Results:* companies that properly implement Six Sigma have seen profit margins grow 20% year after year for each sigma shift (up to about 4.8s to 5.0s. Since most companies start at about 3s, virtually each employee trained in Six Sigma will return on average $230,000 per project to the bottom line until the company reaches 4.7s. After that, the cost savings are not as dramatic.

- *However,* improved profit margins allow companies to create products & services with added features and functions that result in greater market share.

Six Sigma COPIS Model

*O*utputs   *P*rocess   *I*nputs

*P*atients *C*ustomer   *S*uppliers

Steps

How does Six Sigma Work?

The Voice of the Customer (VOC) is aggressively sought and rigorously evaluated and used to determine needed outputs and hence the optimal process configuration needed to yield those outputs and their necessary inputs for which the best suppliers are identified and allied with.

From Concept to Market: the Voice of the Customer

Six Sigma: How Do We Innovate?

Define

Control

Measure

Improve ◄ ∙∙∙∙∙ **A**nalyze

Define *the problem and customer requirements.*

Measure *defect rates and document the process in its current incarnation.*

Analyze *process data and determine the capability of the process.*

Improve *the process and remove defect causes.*

Control *process performance and ensure that defects do not recur.*

"Common sense" doesn't mean "commonly done" or when done, done well.

Six Sigma Innovation & the DMAIC Algorithm

Six Sigma: How Do We Design?

Define

Verify

Measure

Design ◄ ∙∙∙∙∙ **A**nalyze

Define *customer requirements and goals for the process, product or service.*

Measure *and match performance to customer requirements.*

Analyze *and assess the design for the process, product or service.*

Design *and implement the array of new processes required for the new process, product or service.*

Verify *results and maintain performance.*

All new products at GE are designed using a DFSS algorithm.

Design for Six Sigma (DFSS)

It is About the Numbers.

(Assuming Distribution Shift ± 1.5σ)

σ	PPM	COPQ
		Stated as a % of Sales

Many Service firms are here — 2 — 308,537

Many Ave. Mfg firms are here — 3 — 66,807 — 25-40%

Innovative Mfg. firms make it to here — 4 — 6,210 — 15-25% — *The "Six Sigma Wall"*

5 — 233 — 5-15%

Very few are here — 6 — 3.4 — <1%

Process Capability	Defects per Million Opportunities

Sigma (σ) is a statistical unit of measure which reflects process capability. The sigma scale of measure is perfectly correlated to such characteristics as defects-per-unit, parts-per million defective, and the probability of a failure/error.

Let's Put the Lean Process into Perspective

Six Sigma Metric Nomograph

What is Lean?

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➤ Originated within Toyota in 1950's
➤ Its use focuses on elimination of Waste
➤ Enhancing 'Value-Added' operations
➤ A method to reduce complexity and improve process flow

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Cycle Time

Wait Time (non value add)

Work Time (value add)

Before

After

Same work completed in less time

✓ Cost
✓ Defects
✓ Lead time
✓ Inventory
✓ Space
✓ Waste!

✓ Productivity
✓ Customer satisfaction
✓ Profit
✓ Customer responsiveness
✓ Capacity
✓ Quality
✓ Cash flow
✓ On time delivery

Cost/Chaos

Cycle time

Relentlessly focus on reducing non-value adding activities

Define value from the customer's perspective and express value in terms of a specific product

1 Specify Value

2 Map the Value Stream

Map all of the steps – value added and non-value added – that bring a product of service to the customer

LEAN THINKING

BANISH WASTE AND CREATE WEALTH IN YOUR CORPORATION

James P. Womack and Daniel T. Jones

5 Work to Perfection

3 Establish Flow

The complete elimination of waste so all activities create value for the customer

The continuous movement of products, services and information from end to end through the process

4 Implement Pull

Nothing is done by the upstream process until the downstream customer signals the need

The tools get you there… the principles keep you there

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1. Specify Value

A capability provided to a customer at the right time at an appropriate price, as defined in each case by the customer.

✓ *Specify value from the standpoint of the end customer*

✓ *Ask how your current products/services and processes disappoint your customer's value expectation:*

➢ *price?*

➢ *quality?*

➢ *reliable delivery?*

➢ *rapid response to changing needs?*

➢ *fundamental definition of the product?*

Waste:

➢ *Activities that add no value, add cost and time*

➢ *Symptoms: need to find root causes and eliminate them*

➢ *7 types of waste:*

1. *(Unnecessary) inventory*
2. *Overproduction*
3. *Waiting*
4. *Transporting*
5. *Inappropriate processing*
6. *Unnecessary motion*
7. *Defects*

Typical operation: 1-10% of activities are value-adding

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2. Map the Value Stream

"Whenever there is a product or service for a customer, there is a value stream. The challenge lies in seeing it."
(Womack, Learning To See)

- Identify all of the steps currently required to move products/services from order to delivery
- Challenge every step: Why is this necessary? Would the customer think the product is worth less if this step could be left out?
- Many steps are only necessary because of the way firms are organized and previous decisions about assets and technologies

Value stream

All activities, both value added and non-value added, required to bring a product (or provide a capability) from raw material (initialization) into the hands of the customer

Necessary behind the scenes work

Pure Waste

Value-adding
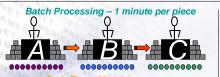
Map the value stream – see the whole and improve the system

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3. Establish Flow

Line up all steps that truly create value in a rapid sequence
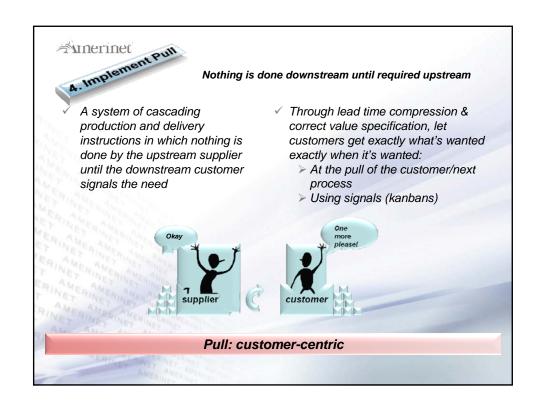
- ✓ Continuous movement of products, services and information through the various transactions from end to end in the process
- ✓ Flow appears impractical and illogical because we have been trained to think in terms of:
  - departments, silos
  - batches, queues
  - efficiencies and backlogs
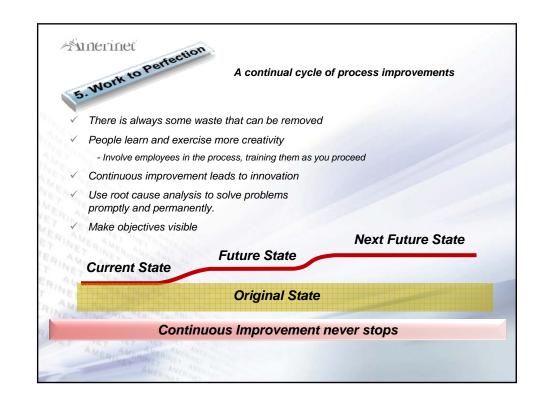
- ✓ Require that every step in the process be:
  - Capable – right every time (six sigma)
  - Available – always able to run (TPM)
  - Adequate – with capacity to avoid bottlenecks <u>and</u> overcapitalization (right-sized tools)

Batch Processing – 1 minute per piece

A → B → C

Cycle Time = 30+ min

Continuous Flow – Make One Move One

A B C

Cycle Time = 12 min

Apply the right tools at the right stage

4. Implement Pull

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Nothing is done downstream until required upstream

✓ A system of cascading production and delivery instructions in which nothing is done by the upstream supplier until the downstream customer signals the need

✓ Through lead time compression & correct value specification, let customers get exactly what's wanted exactly when it's wanted:
  ➢ At the pull of the customer/next process
  ➢ Using signals (kanbans)

Okay

One more please!

supplier   customer

Pull: customer-centric

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5. Work to Perfection

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A continual cycle of process improvements

✓ There is always some waste that can be removed

✓ People learn and exercise more creativity
  - Involve employees in the process, training them as you proceed

✓ Continuous improvement leads to innovation

✓ Use root cause analysis to solve problems promptly and permanently.

✓ Make objectives visible

Next Future State

Future State

Current State

Original State

Continuous Improvement never stops

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Common Lean Tools: Standardized Work

The devil is in the details. If you do not specify the standard, you allow wastes to occur that could be eliminated. But more important, it hinders learning and improvement in the organization.

Specify content, sequence, timing and outcome to prevent and to expose waste. However, keep in mind that the details have to improve the flow of value as drawn in a value stream map.
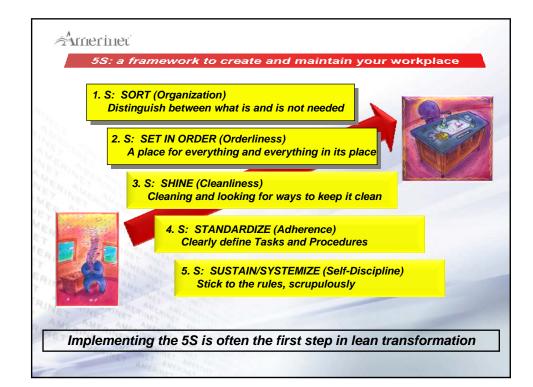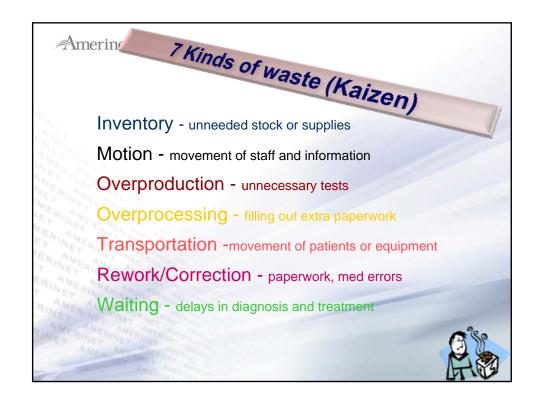

Perfect example of standardized work

1. *Each worker understands their task.*
2. *All tools and equipment are at arms length*
3. *Standard work has been practiced to perfection*
4. *Continuous observation and analysis drives continuous improvement*
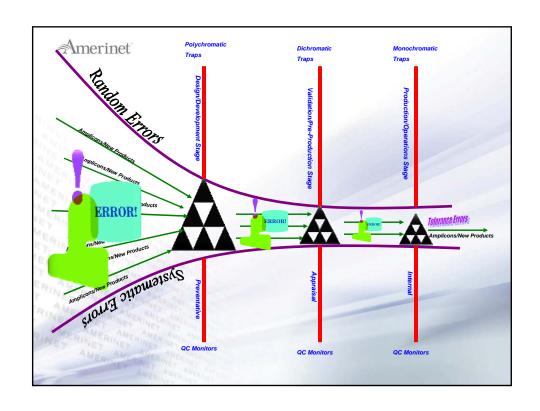
Types of Waste Eliminated
- *Searching*
- *Finding*
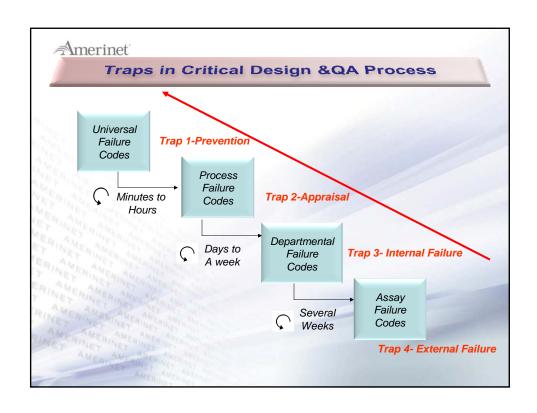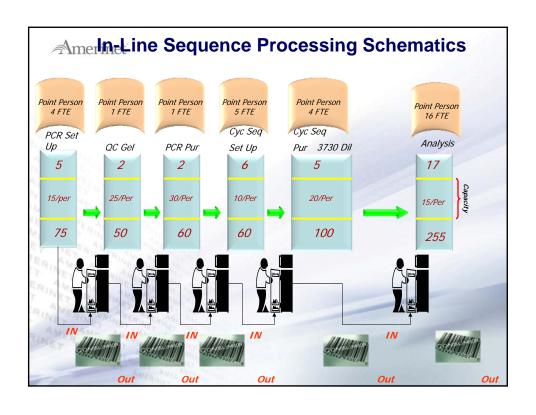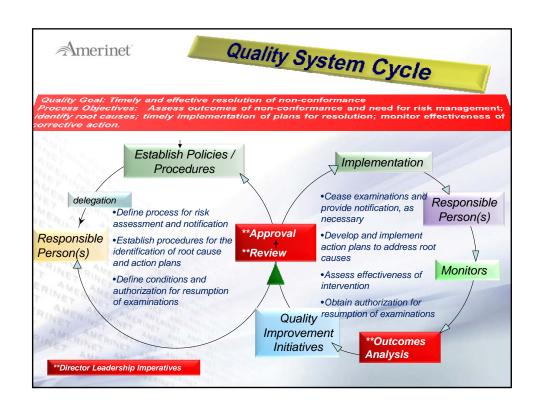- *Selecting*
- *Transporting*
- *Waiting*

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5S: a framework to create and maintain your workplace

1. S: SORT (Organization)
  Distinguish between what is and is not needed

2. S: SET IN ORDER (Orderliness)
  A place for everything and everything in its place

3. S: SHINE (Cleanliness)
  Cleaning and looking for ways to keep it clean

4. S: STANDARDIZE (Adherence)
  Clearly define Tasks and Procedures

5. S: SUSTAIN/SYSTEMIZE (Self-Discipline)
  Stick to the rules, scrupulously

Implementing the 5S is often the first step in lean transformation

5S Workplace Organization

Before 5S

Not Needed

Needed

Create Visual Workplace
- S2: **Set In Order** (Seiton)
- S3: **Shine** (Seiso)
- S4: **Simplify & standardize** (Sieketsu)

(Red Tagged)

S1: Sort (Seiri)

After 5S

Remove from Workplace

Discard after a defined time

-S5: **Sustain** (Shitsuke)

A place for everything and everything in its place

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7 Kinds of waste (Kaizen)

Inventory - unneeded stock or supplies

Motion - movement of staff and information

Overproduction - unnecessary tests

Overprocessing - filling out extra paperwork

Transportation -movement of patients or equipment

Rework/Correction - paperwork, med errors

Waiting - delays in diagnosis and treatment

Traps in Critical Design &QA Process

Universal Failure Codes

Trap 1-Prevention

Minutes to Hours

Process Failure Codes

Trap 2-Appraisal

Days to A week

Departmental Failure Codes

Trap 3- Internal Failure

Several Weeks

Assay Failure Codes

Trap 4- External Failure

The Price of Conformance and Nonconformance (COQ)

Stage of Defect Detection	Costs Include:
Prevention	Design reviews, product qualifications, Materials evaluations, specification reviews, process capability studies, tool control, operation training, acceptance planning, preventive maintenance, and implementation of quality management systems
Appraisal	Post- Launch surveillance, Materials Monitoring and inspections, in process inspections, and final inspections
Internal Failure	Wrong results; rework, repair, scrap, redesign, purchasing and supplier changes & Notifications, corrective actions costs, Adverse Events
External Failure	Instrument repairs; replacement; service after service, loss of market share; lawsuits from injury or property damage

In-Line Sequence Processing Schematics

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Point Person 4 FTE	Point Person 1 FTE	Point Person 1 FTE	Point Person 5 FTE	Point Person 4 FTE	Point Person 16 FTE
PCR Set Up	QC Gel	PCR Pur	Cyc Seq Set Up	Cyc Seq Pur 3730 Dil	Analysis
5	2	2	6	5	17
15/per	25/Per	30/Per	10/Per	20/Per	15/Per
75	50	60	60	100	255

Capacity

IN   IN   IN   IN   IN

Out   Out   Out   Out   Out

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Quality System Cycle

Quality Goal: Timely and effective resolution of non-conformance
Process Objectives: Assess outcomes of non-conformance and need for risk management; identify root causes; timely implementation of plans for resolution; monitor effectiveness of corrective action.

Establish Policies / Procedures

Implementation

delegation

Responsible Person(s)

•Define process for risk assessment and notification

•Establish procedures for the identification of root cause and action plans

•Define conditions and authorization for resumption of examinations

**Approval
**Review

•Cease examinations and provide notification, as necessary

•Develop and implement action plans to address root causes

•Assess effectiveness of intervention

•Obtain authorization for resumption of examinations

Responsible Person(s)

Monitors

Quality Improvement Initiatives

**Outcomes Analysis

**Director Leadership Imperatives

What is the Current Convergence that Enables Something Transformative to Happen in Healthcare?

1) **Healthcare reform-** Changing the payment incentives to align hospital and physician financial gains, penalizing hospitals for re-admissions, and fund new models for care delivery for chronic disease management.

2) **Performance Transparency-** showing healthcare fallacies and failures through validated and reliable benchmarked dashboards. Then use the new matrices to develop incentives in reducing COPQs.

3) **Consumerism-** Empowering the patients to choose regarding what care to seek and where.

4) **Molecular Medicine-** Redefining the nature of disease manifestations (forecasting) and targeting therapies to narrow down cohorts of patients.

5) **Global Connectivity-** Enabling "cognitive" care to be provided at a distance via virtual networks.