

Coordinating Clinical Laboratory and Anatomic Pathology Services in Today's Integrated Clinical Care Continuum

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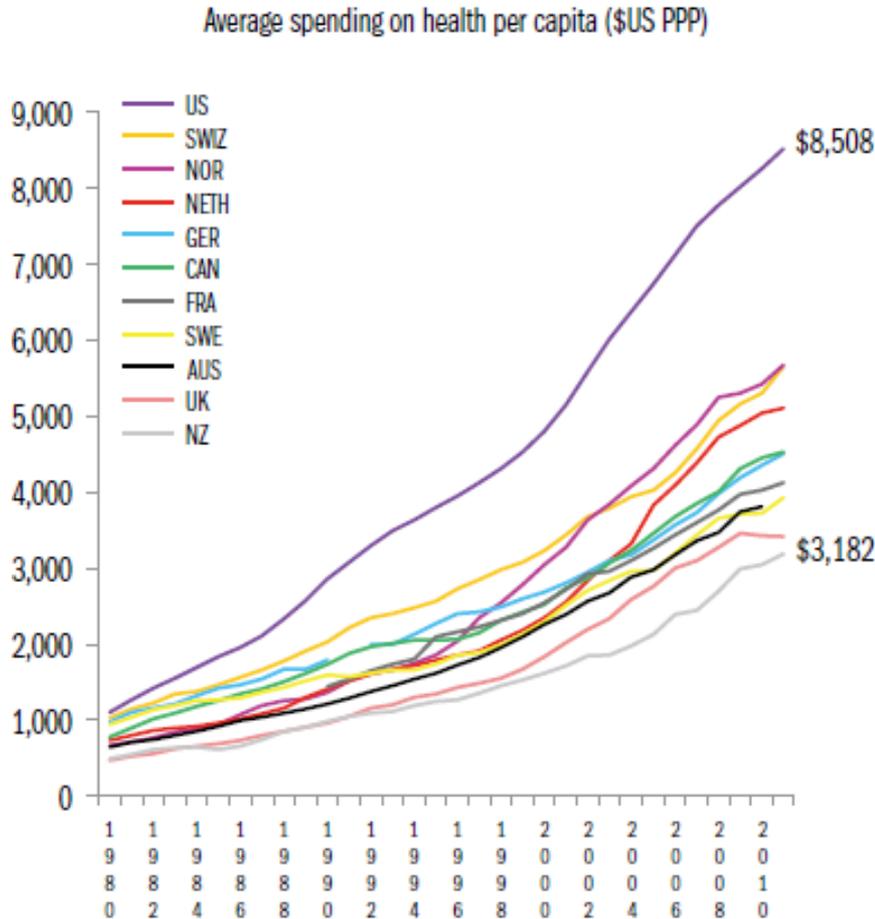
Henry Ford Health System, Detroit

Key Learning Objectives

- To learn how an integrated laboratory service can leverage quality management thinking, Lean and ISO to improve testing service levels and capabilities that provide enhanced value to clinician practices
- To understand the critical role of designing and implementing systems and subsystems of management that focus on lab quality and cost control
- To understand the V-(alue) metrics of importance in defining the value of the medical laboratory and the pathologist in the changing clinical care continuum

Volume Driven Healthcare

Incentive: Do More



Note: \$US PPP - purchasing power parity.

Source: Organization for Economic Cooperation and Development, OECD Health Data, 2013 (Paris: OECD, Nov. 2013).

Efficiency Ranking
 High Income nations
 Increased life expectancy
 relative to \$ spent
 US ranking = 22 of 27
 Life expectancy
 15 days/ additional \$100 spent

Barthold B et al. Analyzing Whether Countries Are Equally Efficient at Improving Longevity for Men and Women. Am J Pub Health 2013 doi: 10.2105/AJPH.2013.301494

Value Driven Healthcare

Incentive: Do Better

ACA Triple Aim



Improve
Health of
INDIVIDUAL

Coordinated Care
Better Outcomes



Improve
Health of
POPULATION

Expanded Coverage
Chronic Care Mgmt
At Risk Mgmt
EHR Use



Spend less
on services
PER CAPITA

Bend the Cost Curve
Reduced
Reimbursements

Paradigm Change

Volume → Value

- **New** delivery care models

- ↑ efficiencies, coordination of care, outcomes, satisfaction

- ↓ spending \$\$

- ACA- ACOs, Medical Homes

- Hospital consolidations & acquisition priv practices

- Clinically integrated private physician networks

- **New** payment models

- Pay-for-Value reimbursement

- PQRS, HCAHPS, Medicare Shared Savings Program

- ↑ primary care pay and ↓ specialty care pay

- PAMA 2014 clinical lab reimbursement reductions

- 30% 2017-2019 (10%/yr); 45% 2020-2022 (15%/yr)

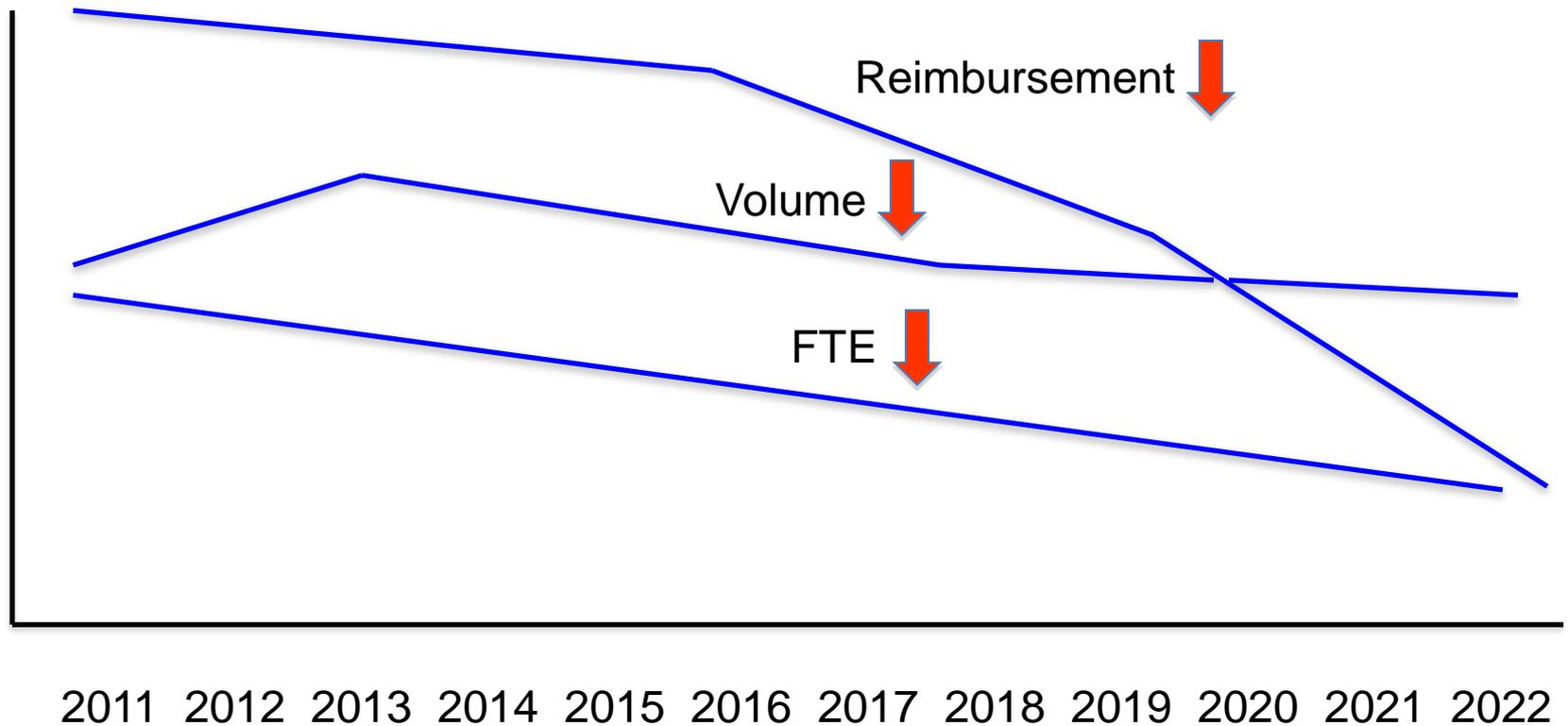
Survival

Hear the wave before you see it



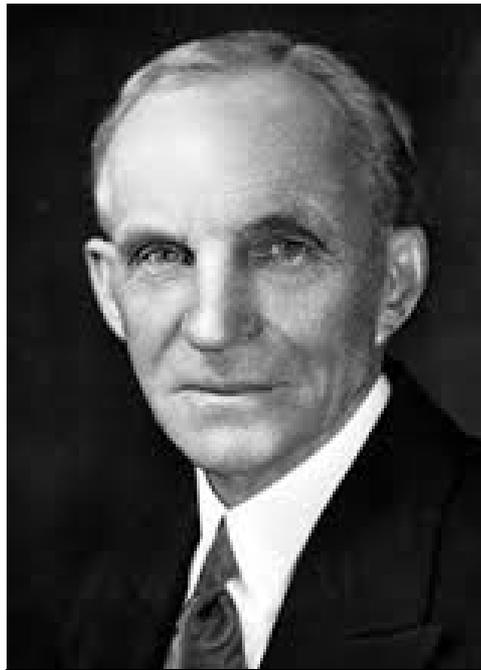
“If you don’t like change, you will like irrelevance even less”

-Gen. Eric Shinseki



A3 Problem Solving

| ← Plan → | ← Do-Check-Act → |
|---|---|
| <p><u>Problem Background</u> The Laboratory is unrecognized as an asset to coordinate care, foster health system integration and cost control. More likely seen as cost center.</p> | <p><u>Implementation Plan</u></p> <ol style="list-style-type: none"> 1. Non-conformance management- Work waste 2. Daily management (QTIPS) -Critical values 3. Test utilization management, Lab Formulary 4. Personalized care management- Molec tests 5. Hospital IPD LOS improvement, MALDI-TOF 6. Pathologists as teachers & consultants |
| <p><u>Hypothesis</u> We have either not created systems to do so or articulated the case for high value well.</p> | |
| <p><u>Current Condition</u></p> <ul style="list-style-type: none"> •3% of the cost; 70% of the EMR •Up to 90% clinical decision-making •Declining hospital revenue, staff reductions •Undeveloped lab systems to support call for co-ordination of care, system integration, cost cntrol | |
| <p><u>Problem Analysis</u> WHY?</p> <ol style="list-style-type: none"> 1. No one asked us to and it's hard work 3. Hard to quantify clinical and cost success 4. Dont have good metrics to share 5. Dont have approp. management subsystems | <p><u>Results</u> The Value (V) metrics of lab survival</p> |
| <p><u>Target Condition</u> Document & achieve recognition for coordination, care integration & system savings Obtain support for lab innovation & growth</p> | <p><u>Metrics</u></p> <ol style="list-style-type: none"> 1. Defect management, Epic errors Reduction unacceptable specimens, rework \$\$, patient satisfaction 2. Safety, critical value notification failures 3. The V metrics <ul style="list-style-type: none"> - Test referral utilization control & savings - Appropriate therapy guidance & savings - IPD episode cost and LOS savings - Clinical consultation guidance |
| <p><u>Action Plan</u> Create subsystems & metrics to show value</p> | <p><u>Standardization</u> Customer focus in consolidated, integrated systems with ISO standardization, Lean leadership and management</p> |



**Henry Ford
1863-1947**

“The business of management is to manage. The thing to be managed is work”

“We still waste more than we use. We waste men, we waste materials, we waste everything, and consequently we have to work too hard and too long to accomplish what in the end amounts to very little.”

“It’s the work not the man that manages”

The Value (V) KPI Metric

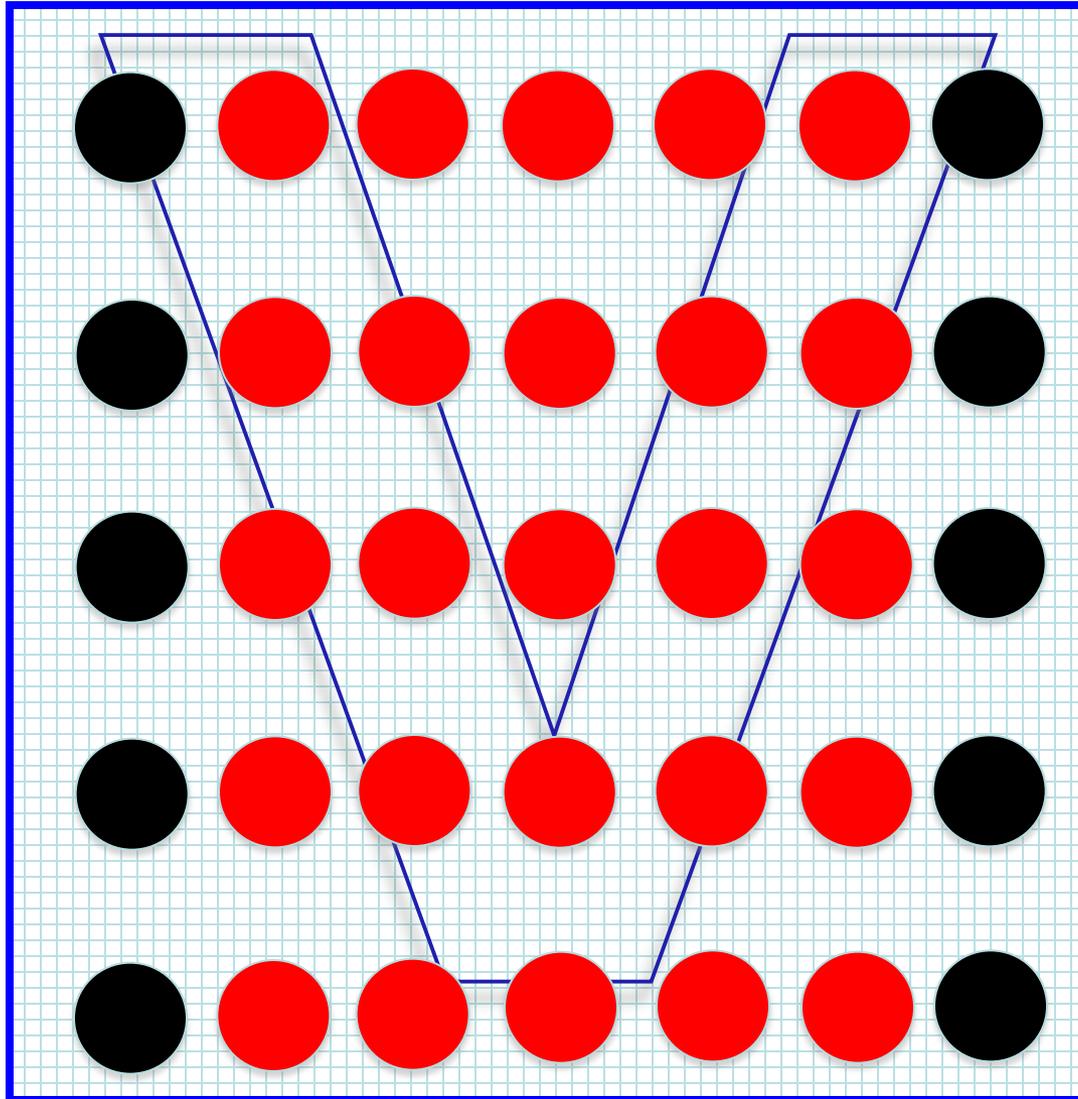
- The currency of healthcare is now \$\$ rather than time -John Waugh
- Are you still pursuing TAT as your lab's measure of success?

Performance => Productivity => Value \$\$ Metrics

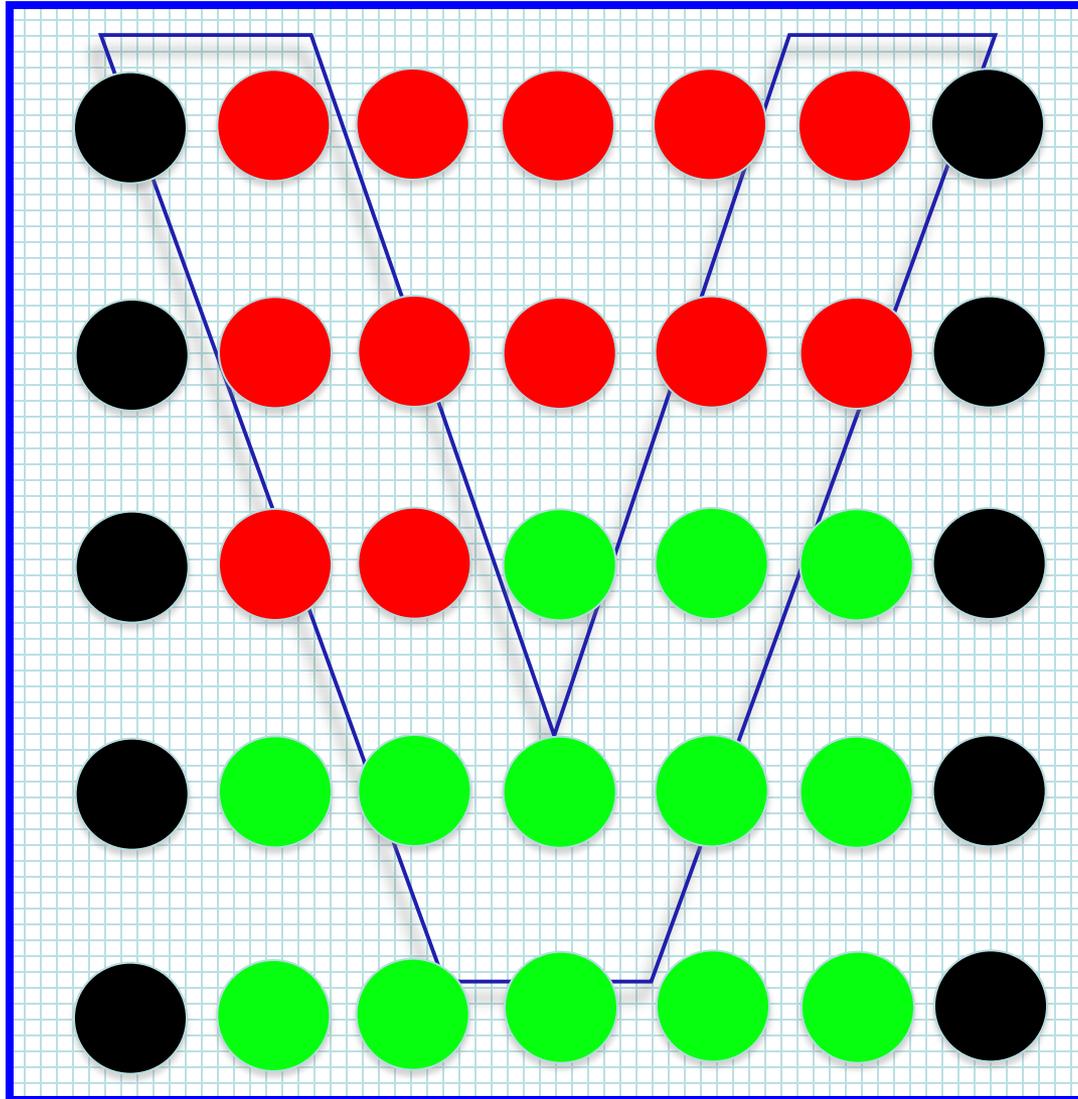


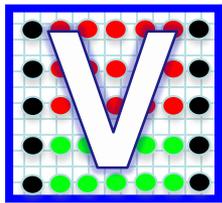
**Cost per test, cost per episode of care, cost control, cost avoidance
Lab costs per adjusted discharge**

The VALUE Metric



The VALUE Metric





Customer Satisfaction in consolidating & integrating systems

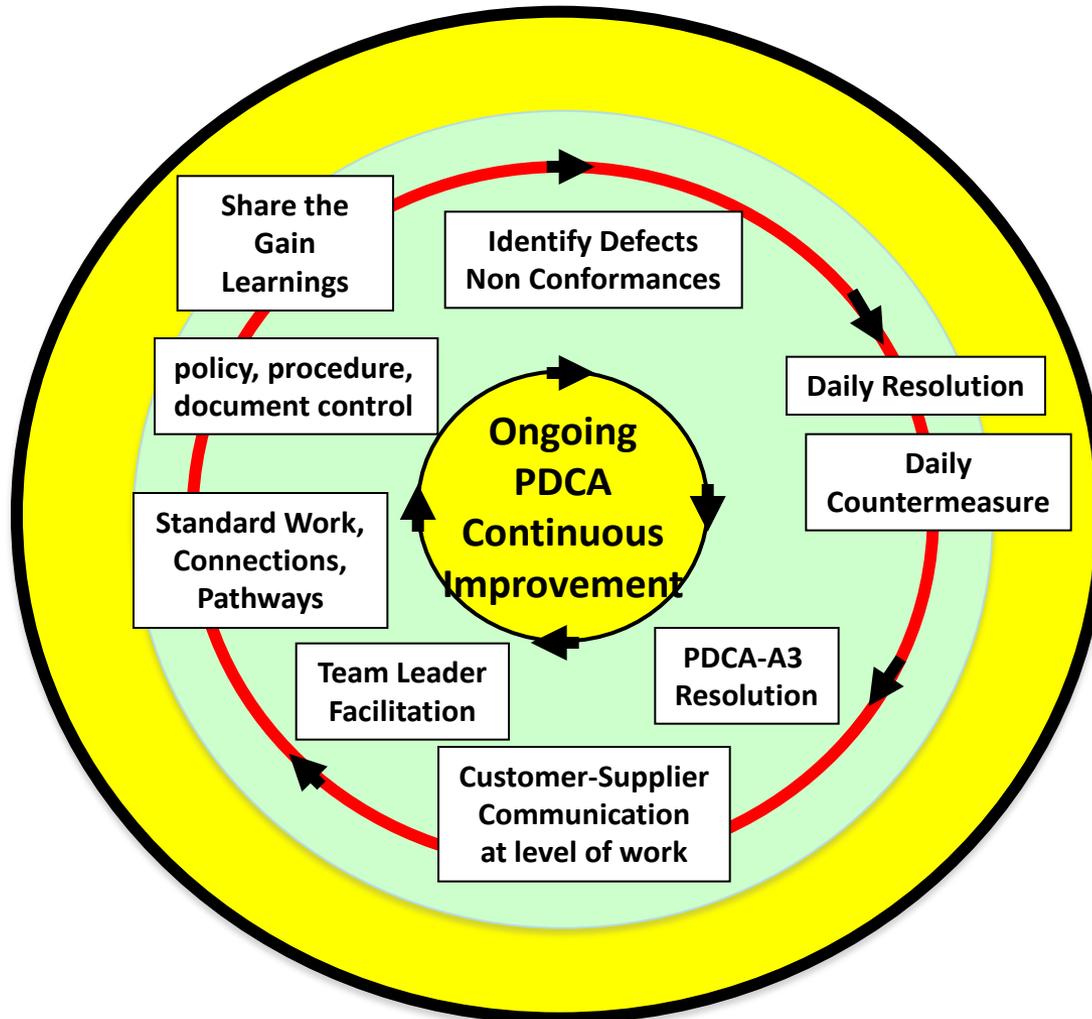
Leverage Lean & ISO Management Systems

“Systems don’t produce quality, people do”

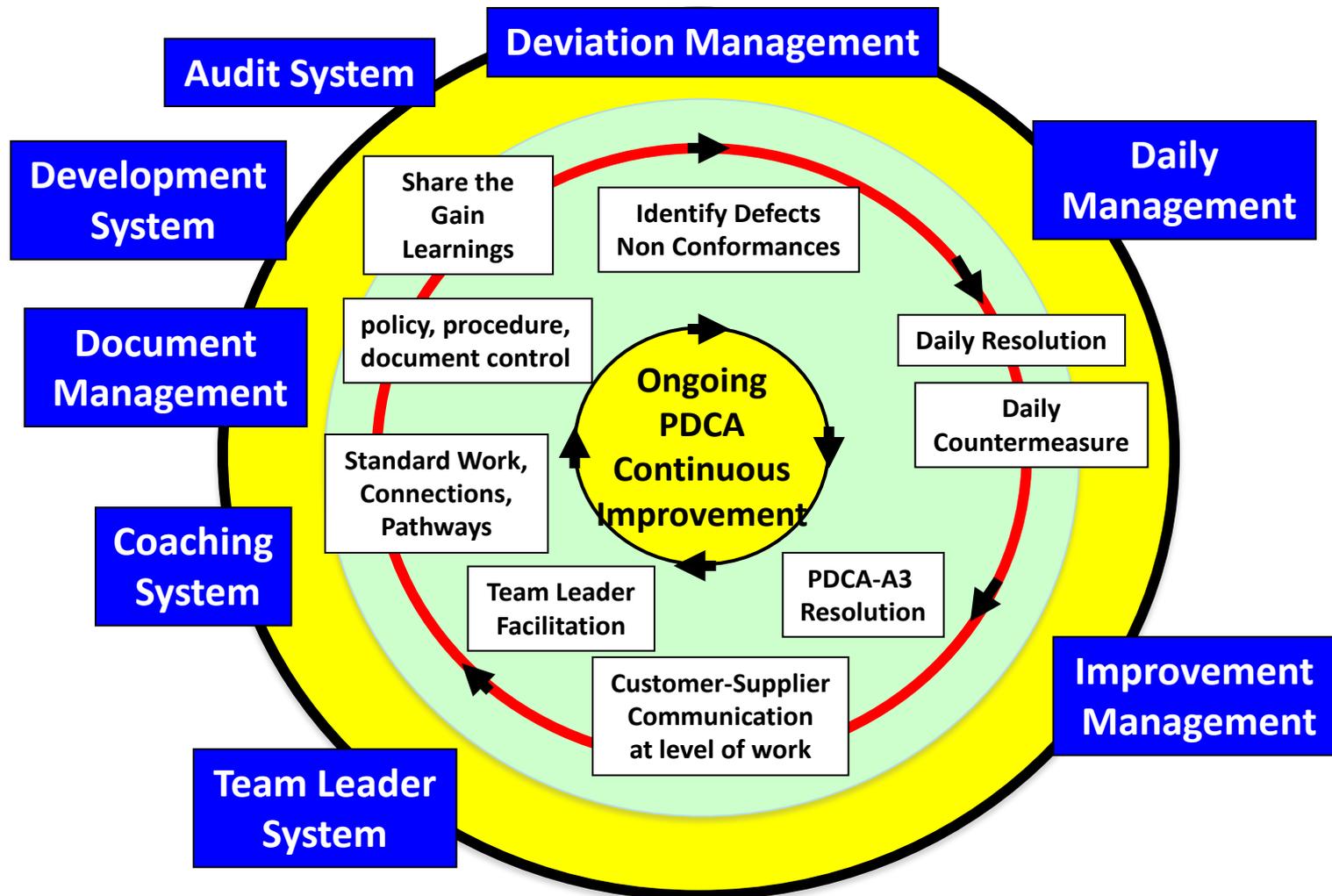
But systems provide standardization for people to:

- Deliver high quality consistently
- Focus on specific requirements of new and existing customers
- Identify poor quality rapidly and correct non-conformances
- Engage the workforce in continuous improvement
- Adopt preventive, not just corrective actions

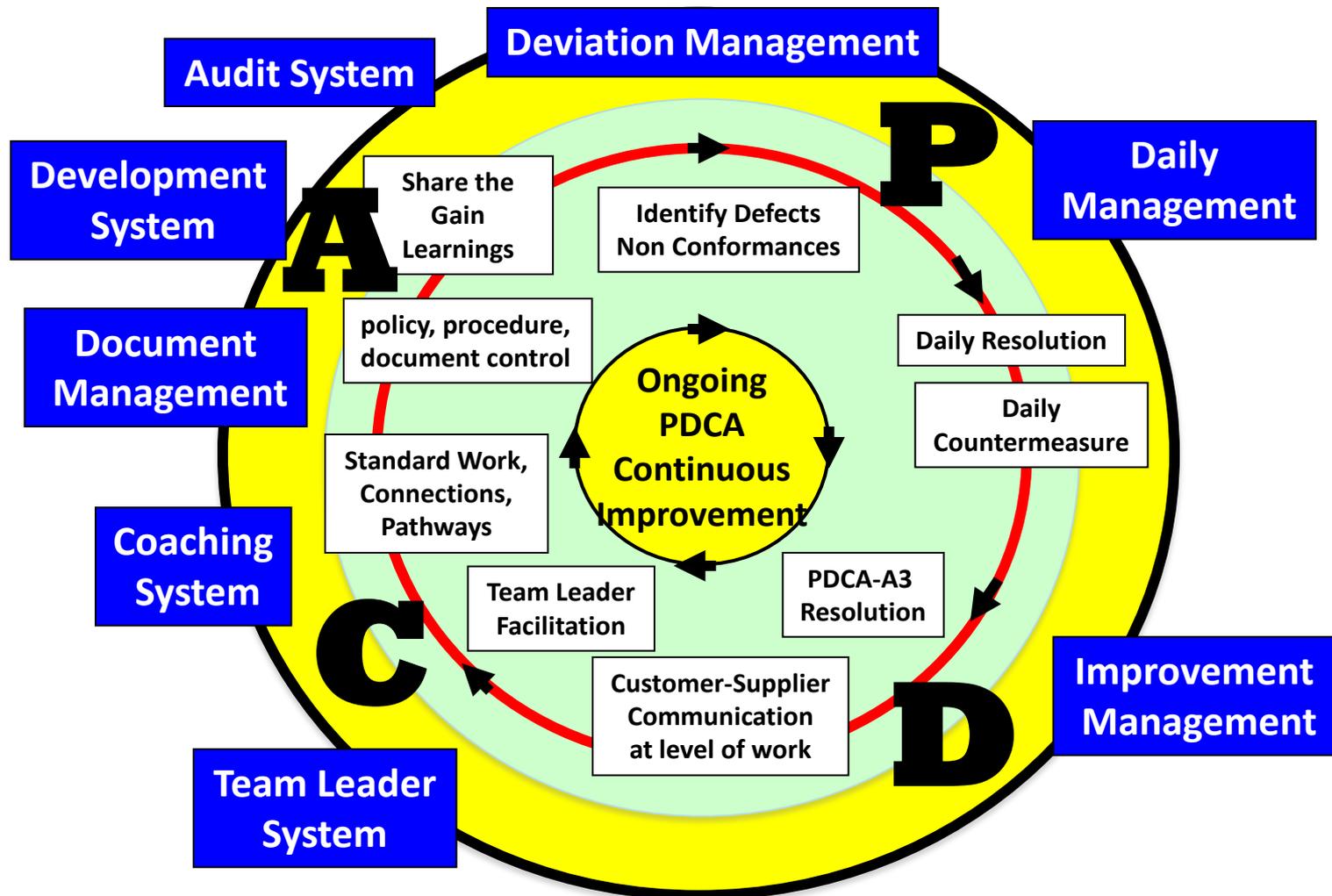
The Processes of Managing for Continuous Improvement



The Processes of Managing for Continuous Improvement



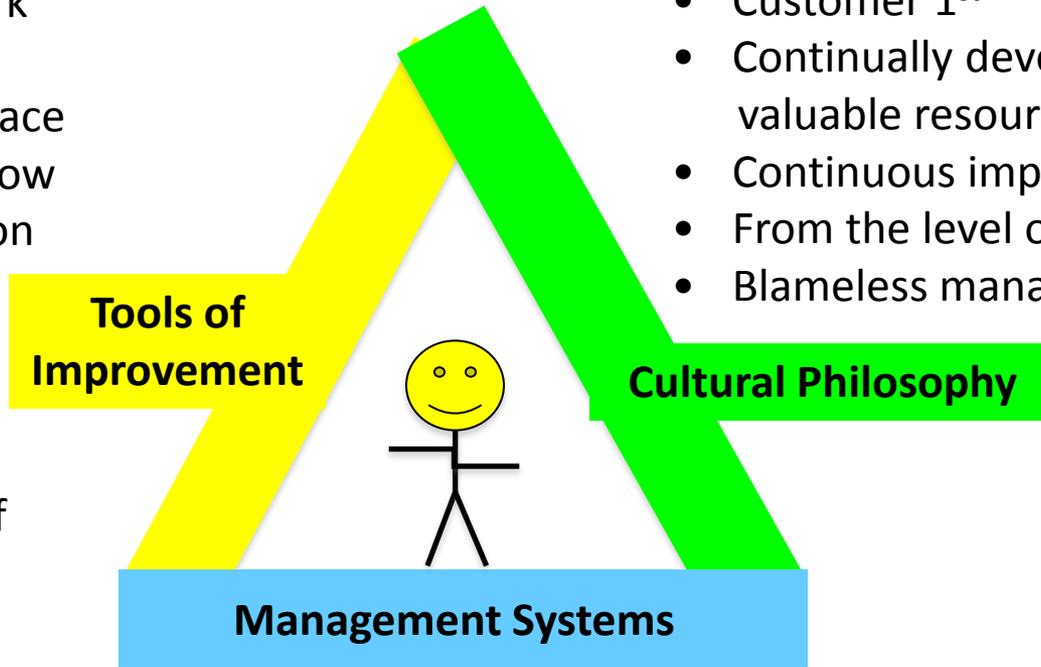
The Processes of Managing for Continuous Improvement



Integrated System

Culture of Continuous Improvement

- Standard Work
- 5S
- Visual workplace
- Continuous flow
- Pull production
- Kanban
- Just in Time
- Load leveling
- Batch size
- Mistake proof



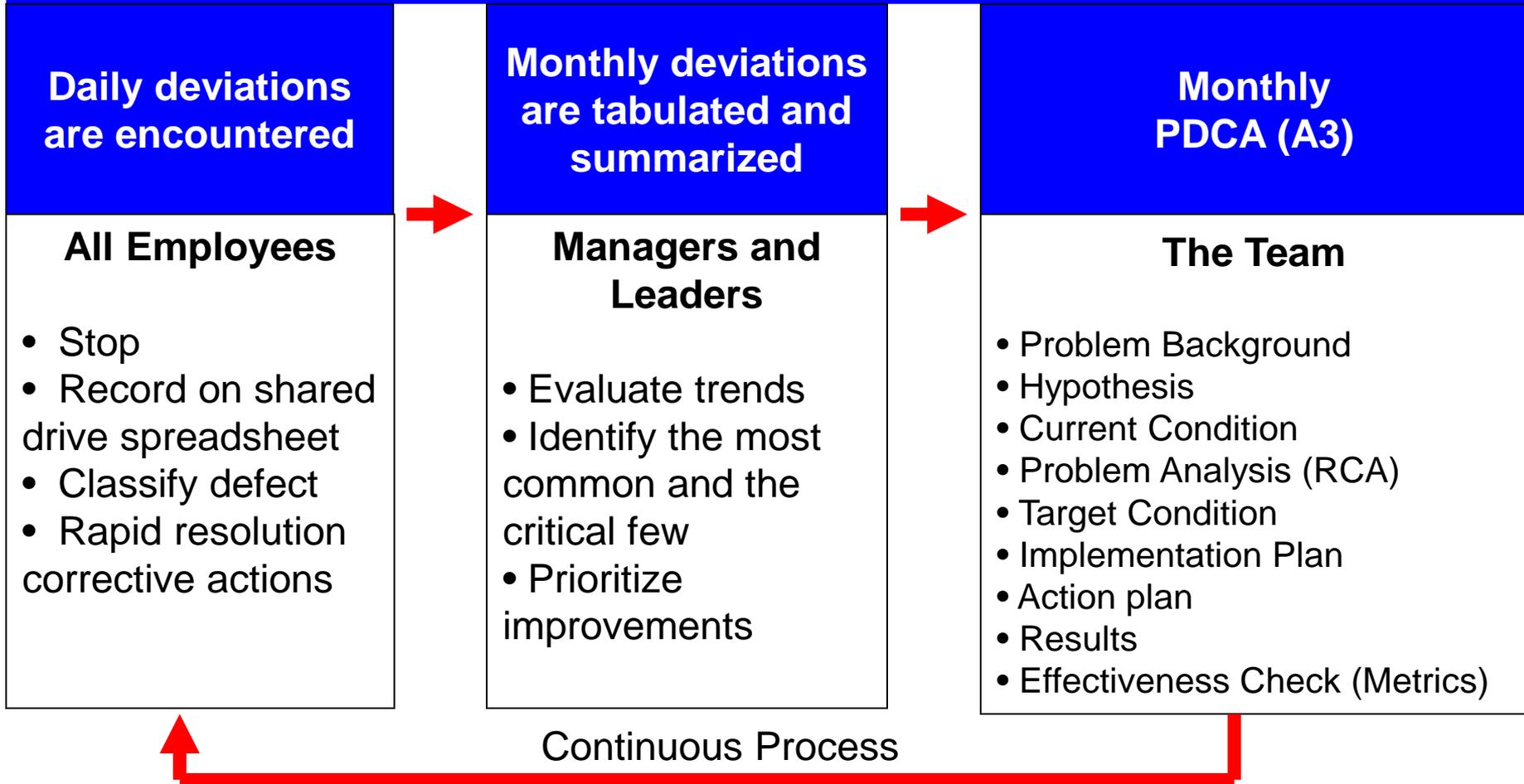
- Customer 1st
- Continually develop your most valuable resource, your PEOPLE
- Continuous improvement
- From the level of the work
- Blameless management

- Hoshin Planning/Policy deployment
- Team leader system
- Improvement management (kata)
- Coaching and development (kata)
- Deviation management
- Daily management
- Document management



Non-Conformance Management

Deviation Management Process



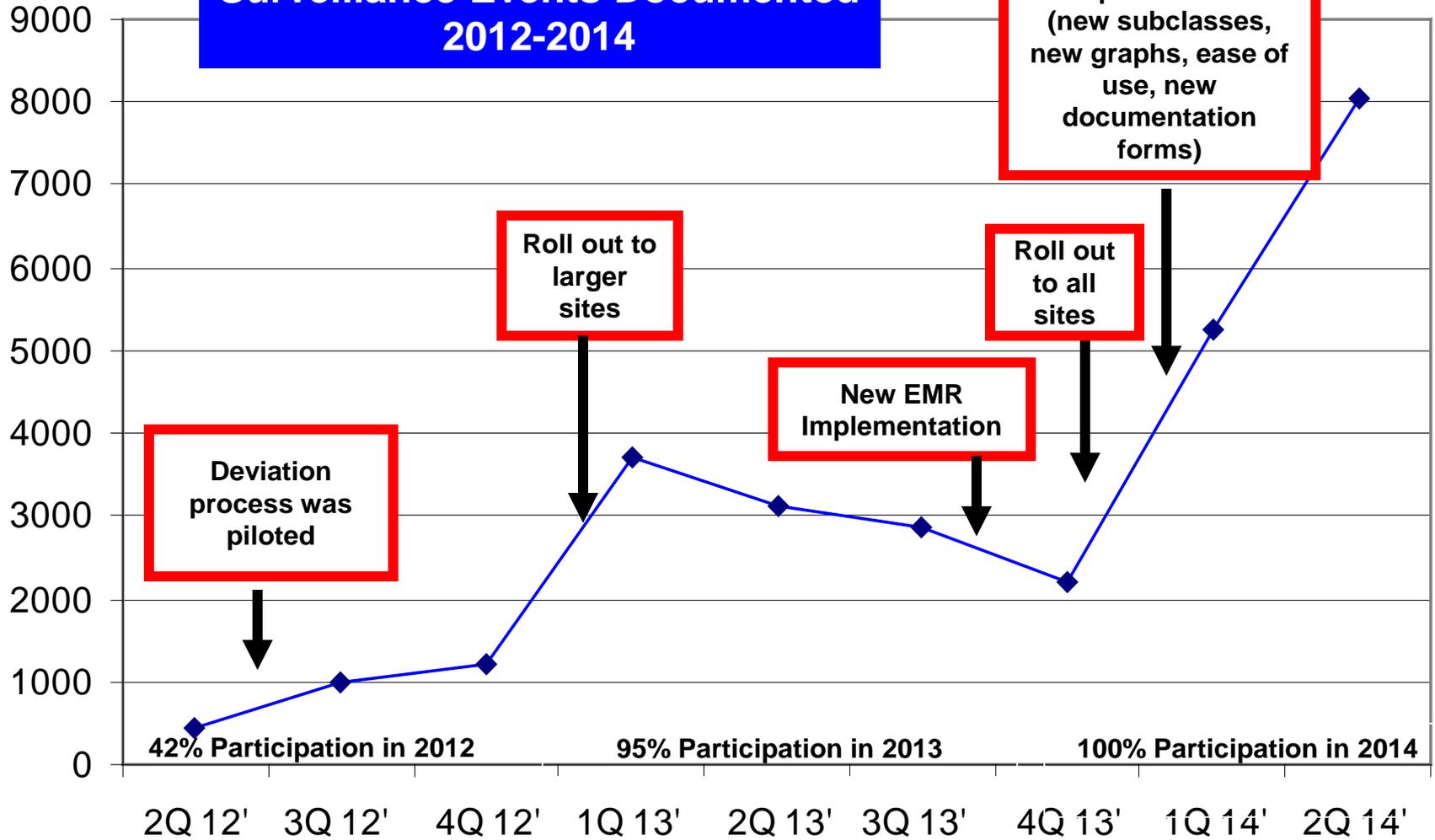
Taxonomy

Deviation Classification Categories

| Main Categories | Number of Subclassification Categories |
|--|---|
| Order Defects | 36 |
| Specimen Defects | 13 |
| Testing Defects | 38 |
| Report Defects | 12 |
| System Online Incident Report (RadicaLogic) | 3 |
| Complaints | 4 |
| Safety | 2 |

Deviation Management Progression

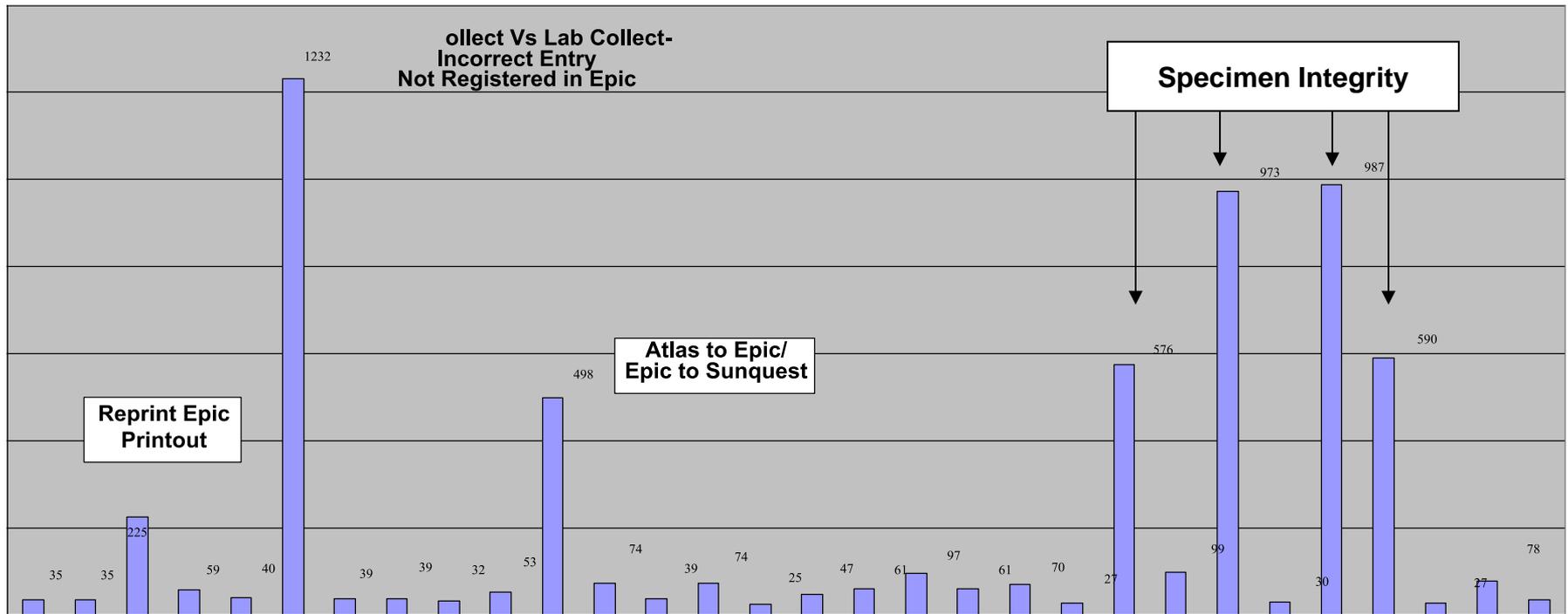
**Surveillance Events Documented
2012-2014**



Deviation Management Surveillance Trending

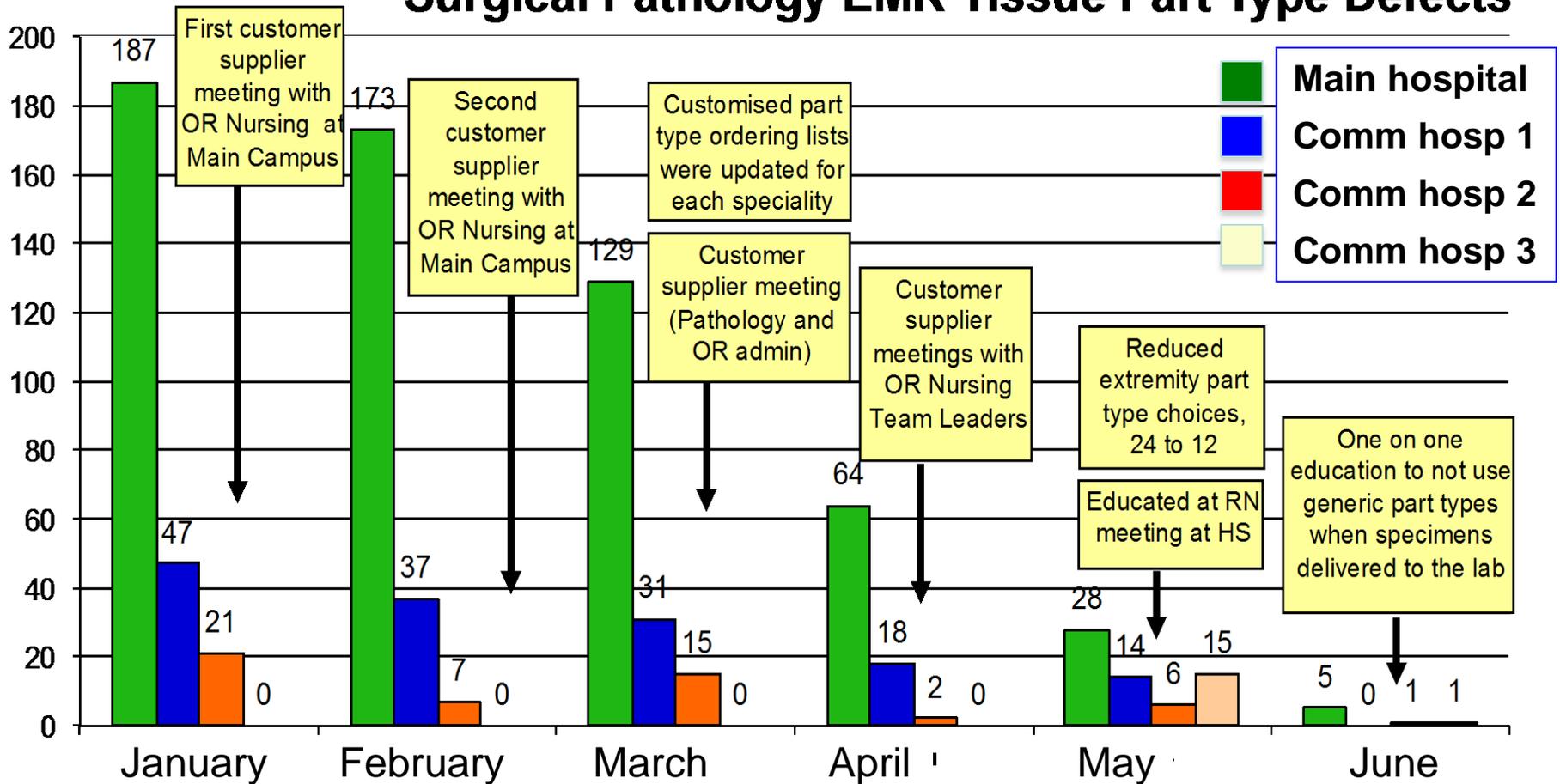
Time = \$\$
 Redraw = dissatisfaction
 Integrity = safety

Top 35 Defects



Epic Orders Improvement- All Hospitals

Surgical Pathology EMR Tissue Part Type Defects





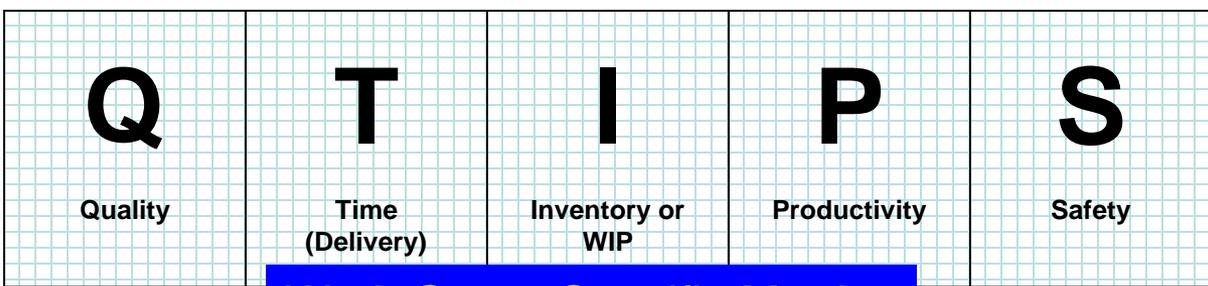
Daily Management



“A legacy of quality”

Daily Management Board

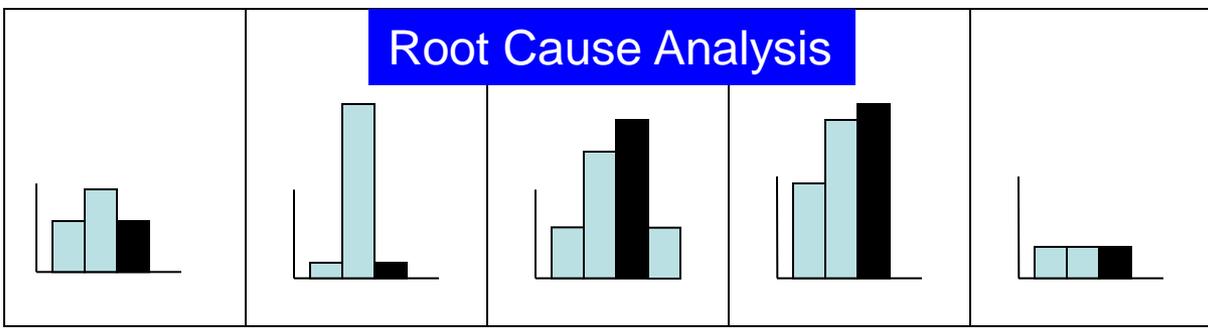
| | | | | |
|---------------------|------------------|-----------------------------------|--------------------------|--------------------|
| Q Quality | T Time | I Inventory (or WIP) | P Productivity | S Safety |
|---------------------|------------------|-----------------------------------|--------------------------|--------------------|



Work Group Specific Metrics



Daily, Weekly, Monthly, Annual Trends



Root Cause Analysis

**Corrective
Actions**

**Preventive
Action Plan**

Visual Management At-a-Glance
DAILY Gemba Rounds with workers

- Each square has all days of month
- Color each per performance
- **RED: METRIC FAILED THRESHOLD**
- **GREEN: METRIC MET THRESHOLD**

Trendlines

- Trend challenging metrics
- Day, week, month, year...
- **BLUE: THRESHOLD**
- **RED: TIME OF FAILURE**
- **GREEN: TIME PASSING THRESHOLD**

Pareto Charts, RCA etc.

| | |
|------|------|
| What | When |
| Why | How |

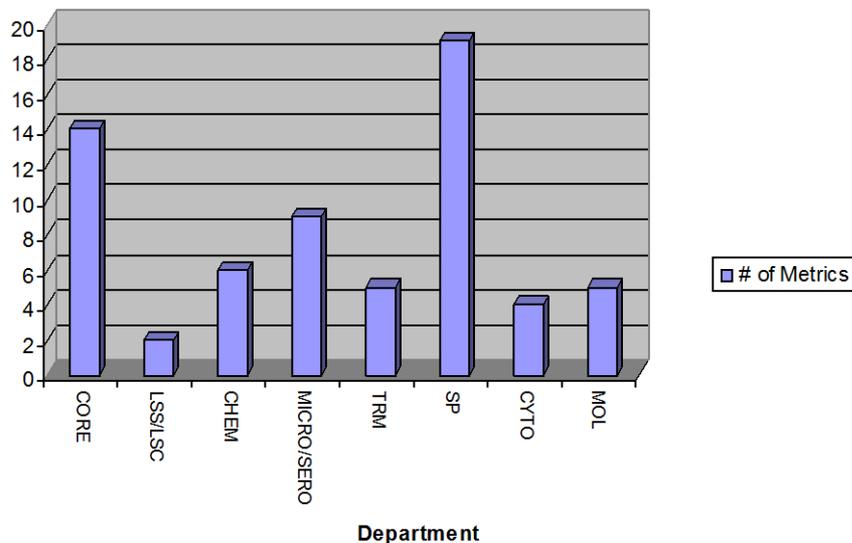
Countermeasures:
Corrective & Preventive Actions
Assign responsibility and
Accountability for completion

Associated PDCA - A3 Projects

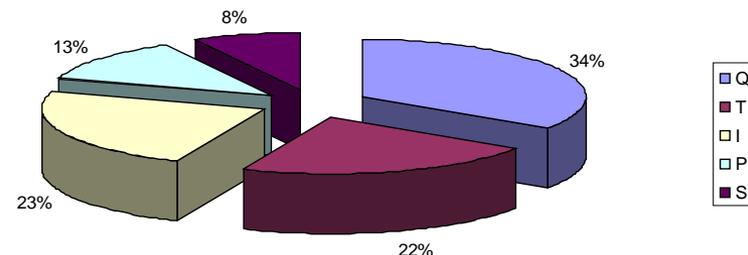
DM Metrics June 2013-2014

| LAB Division | No. Daily Metrics in 1 yr | No. Long term >6 mo | No. Short term 1-6 mo | No. derived process improvements | Q | T | I | P | S |
|--------------|---------------------------|---------------------|-----------------------|----------------------------------|-----------|-----------|-----------|----------|----------|
| Core Lab | 14 | 12 | 2 | 8 | 1 | 5 | 6 | - | 2 |
| Lab Support | 2 | 1 | 1 | 1 | 1 | - | - | 1 | |
| Chemistry | 6 | 6 | - | 4 | 3 | 2 | - | - | 1 |
| Micro/Sero | 9 | 9 | - | 6 | 2 | 1 | - | 6 | - |
| Transfusion | 5 | 5 | - | 2 | - | - | 5 | - | - |
| Surgical | 19 | 11 | 8 | 17 | 10 | 4 | 4 | - | 1 |
| Cytology | 4 | 4 | - | 1 | 1 | 2 | - | - | 1 |
| Molecular | 5 | 5 | - | 3 | 4 | - | - | 1 | - |
| Total | 64 | 53 | 11 | 42 | 22 | 14 | 15 | 8 | 5 |

No. Unique Metrics/Year



QTIPS Domain Usage



Safety



Owners: Jackson/
Smothers/Rahman

Month: August 2013

Meeting Time: 11:30

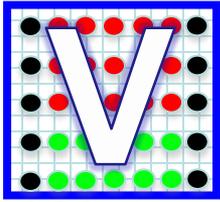
Metric:

All CVs called: green

Any CVs missed: red

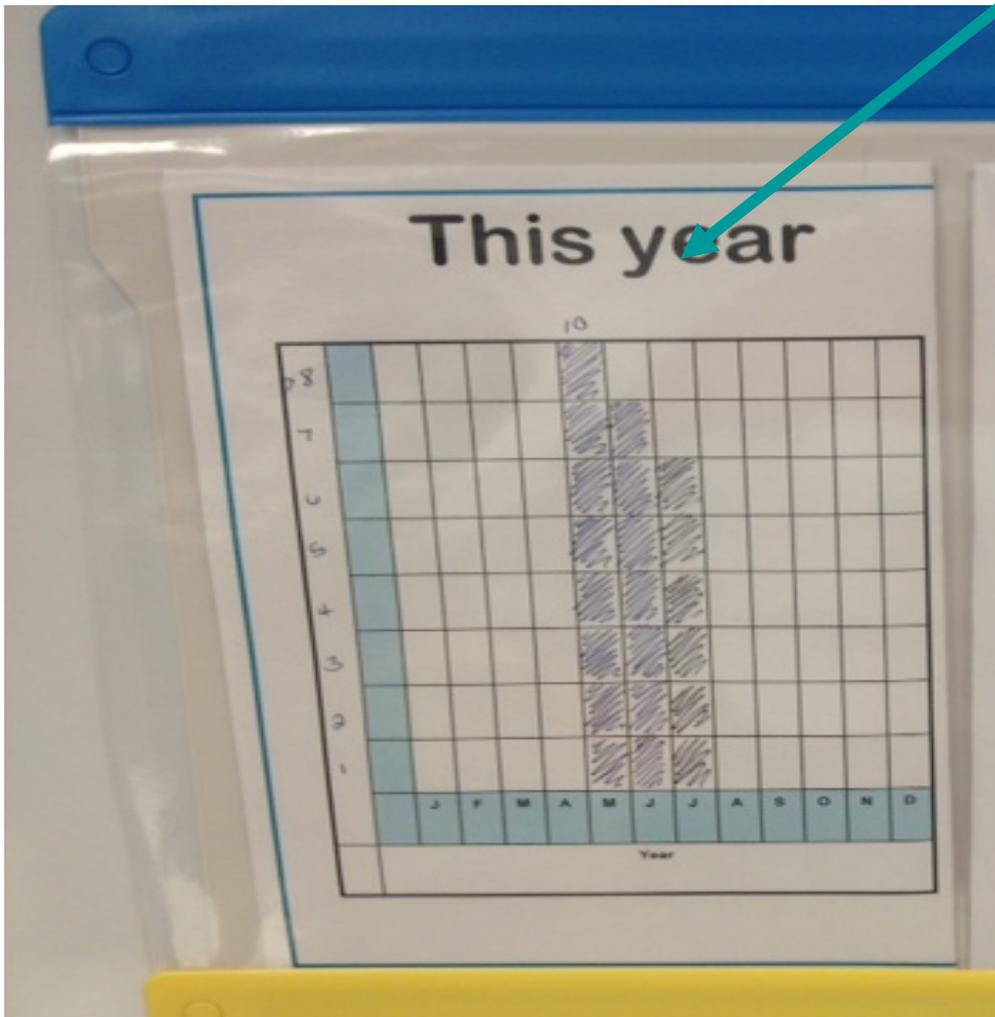
Chart Jacket® Reorder at Magnataq.com/cik US Patent #



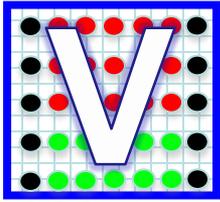


Critical Value Defect Rate

First 3 months...

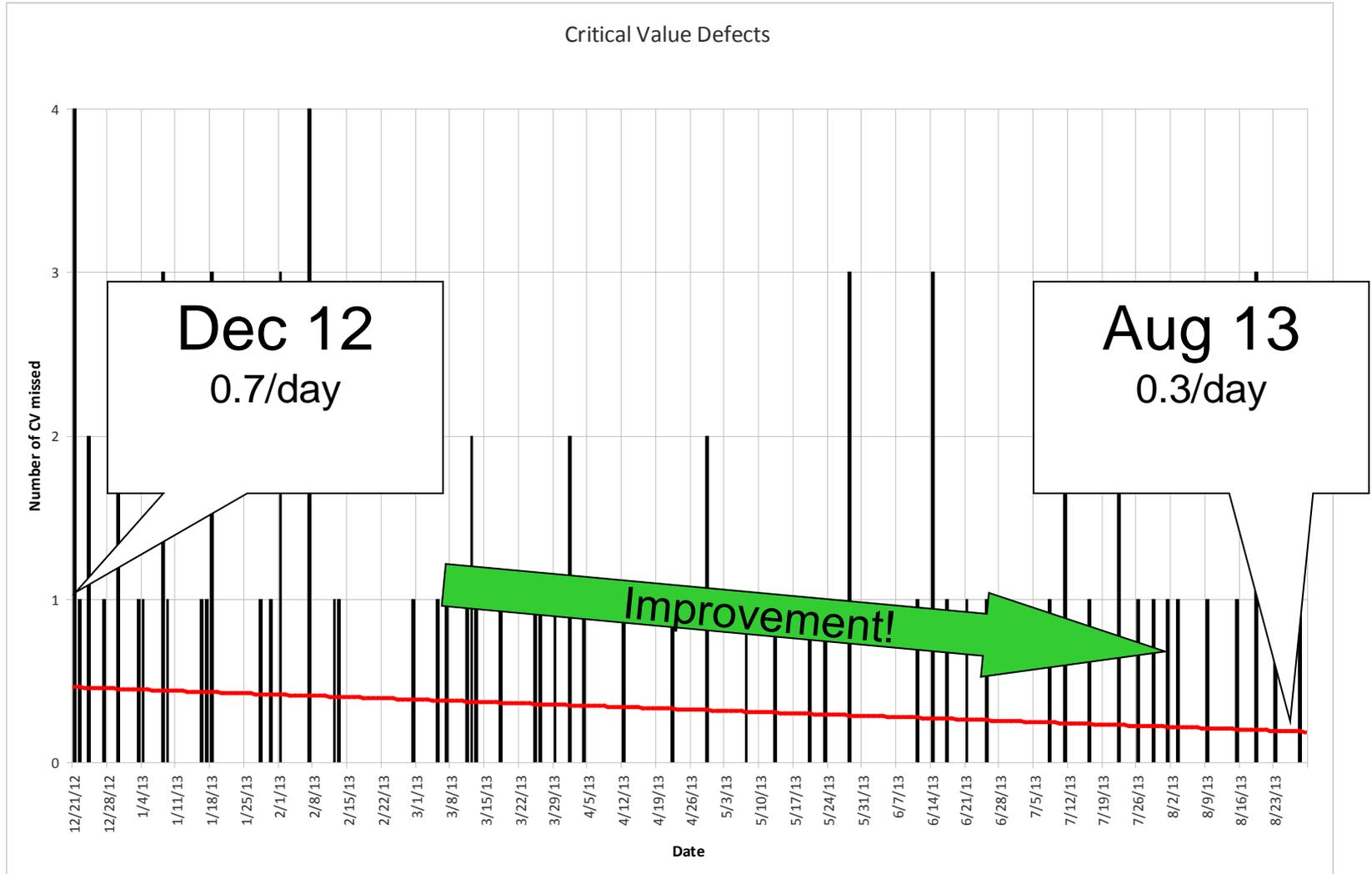


Steady
Drop in
Critical
Value
Callback
Failures

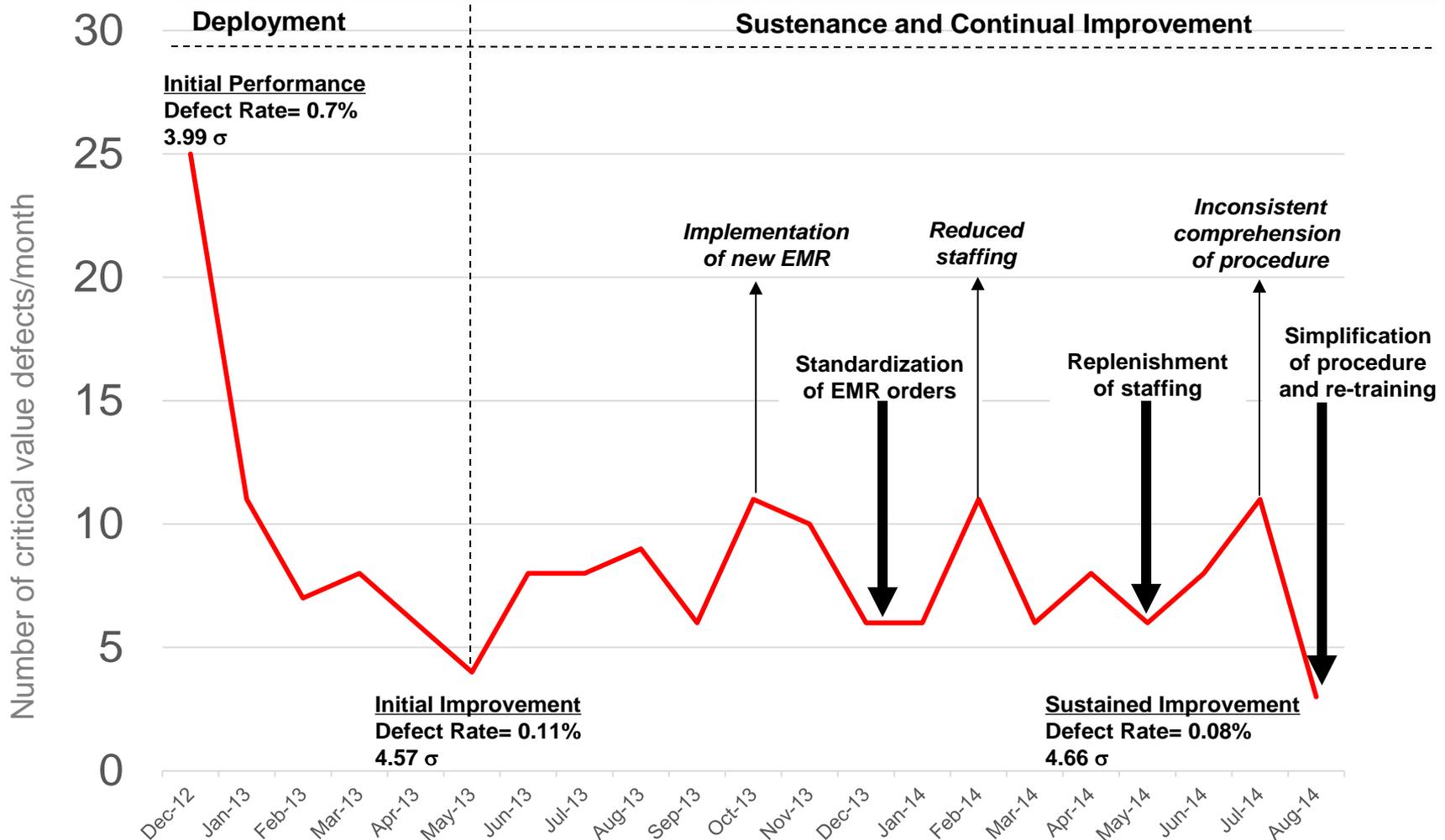


Critical Value Defect Rate

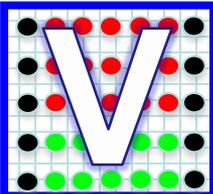
First 8 months...



Sustained Success !



Reduction in Critical Value Defects. This graph represents the improvement in the performance of our laboratory's safety (S) metric related to notification and documentation of a critical value notification to an ordering provider. It represents the initial gains in performance during deployment (December 2012-May 2013), subsequent monitoring of performance (April 2013-August 2014) impacted by varied root-causes (\uparrow) and improvements through countermeasures (\downarrow).



Personalized Cancer Care Management

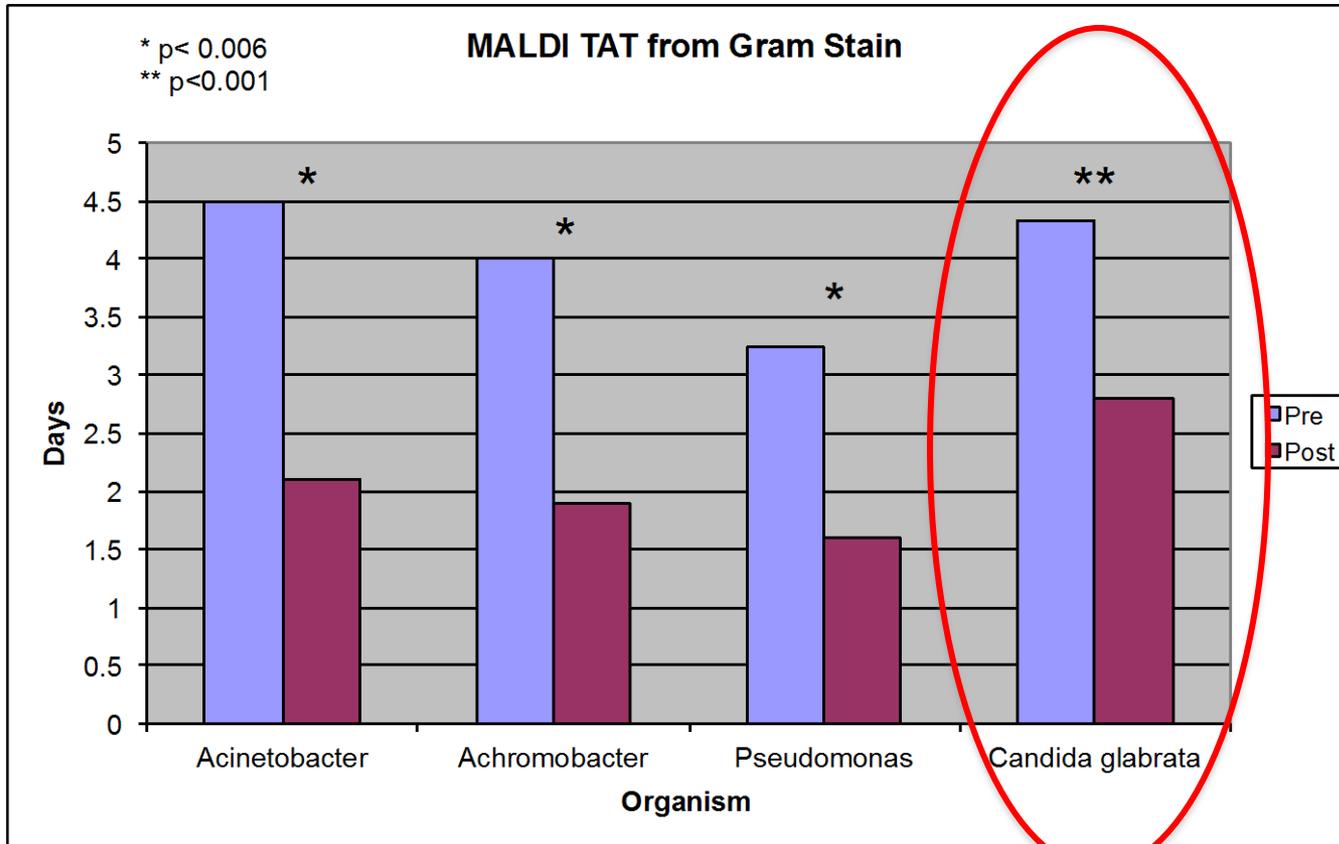
| | | | | 2012 | 2013 |
|--|----------|-------------------|---------------------|---------------------|---------------------|
| Molecular Profile Targeted Therapeutic | | Cost of Treatment | Pharma Cost Savings | Pharma Cost Savings | Pharma Cost Savings |
| EGFR (Gefitinib) | lung | \$72,000 | \$14,184,000 | \$14,832,000 | |
| ALK FISH (Crizotinib) | lung | \$72,000 | \$12,600,000 | \$13,248,000 | |
| BRAF (Ipilimumab) | melanoma | \$120,000 | \$1,560,000 | \$2,880,000 | |
| Her2 FISH (Herceptin) | breast | \$70,000 | \$12,180,000 | \$14,560,000 | |
| KRAS (Cetuximab) | colon | \$125,000 | \$5,750,000 | \$4,750,000 | |
| Testing cost | -- | -- | (\$253,994) | (\$243,551) | |
| Reimburse | | | \$173,881 | \$176,796 | |
| Pharma cost savings (Neg tests X cost Rx) | | | \$46,274,000 | \$50,270,000 | |



Hospital LOS Improvement

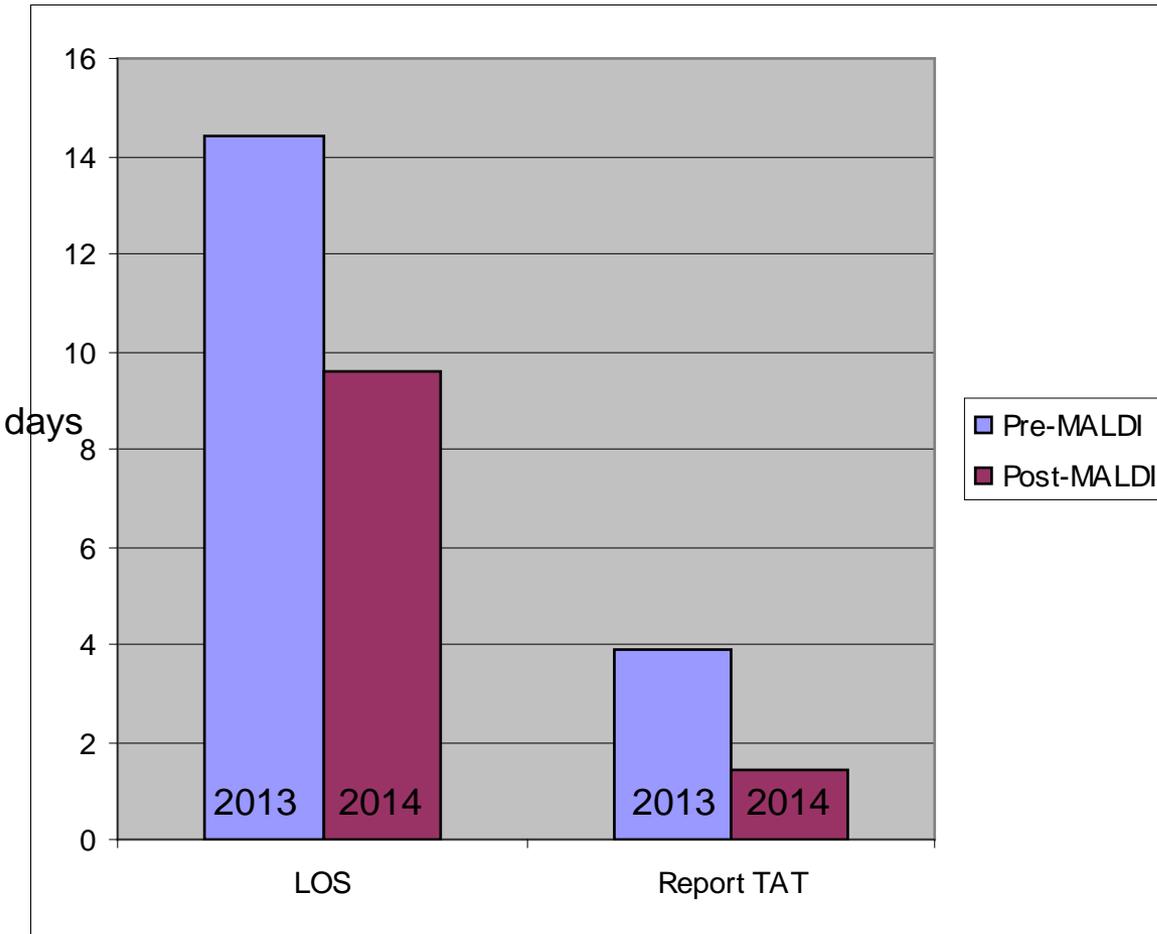
Infectious Disease Episode of Care

Performance Metric TAT Blood Culture Pre & Post MALDI-TOF



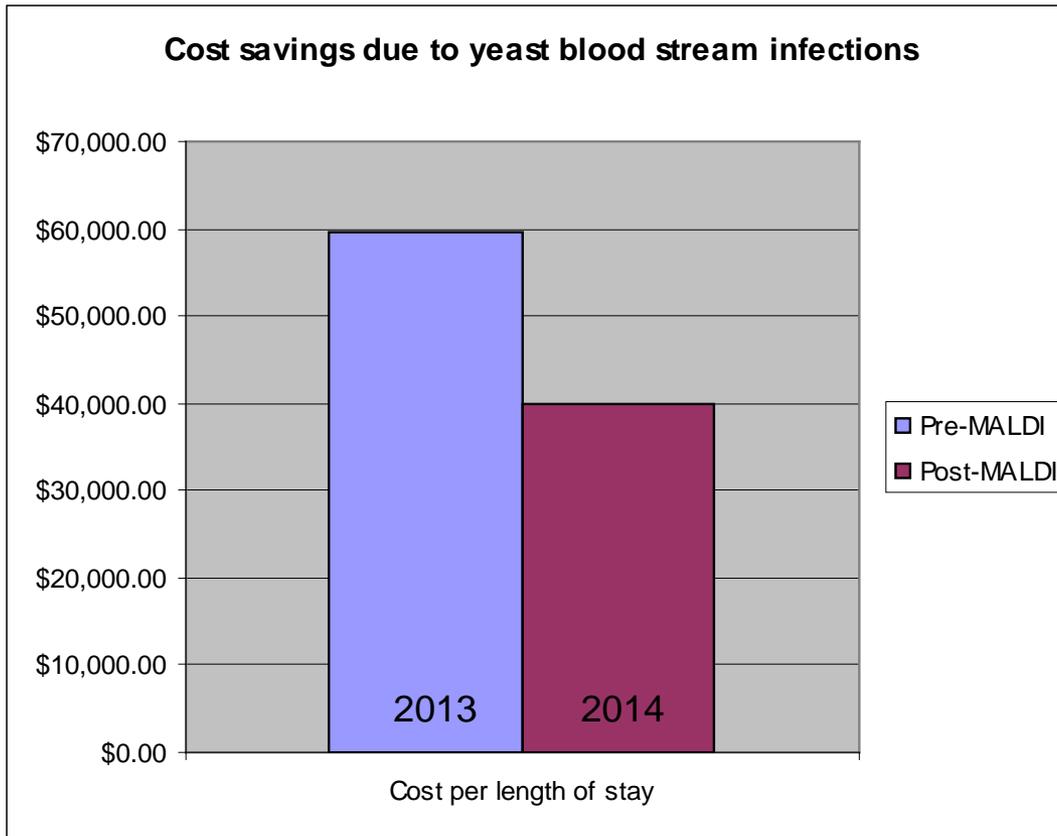
- ~33% decrease overall TAT ID reporting
- Annual lab testing cost savings = \$115,000

V-Metrics LOS & Cost/LOS



- ~33% decrease in overall TAT ID report translates to:
- ~33% decrease LOS (~14 to 9 days)
- LOS = \$4147/day

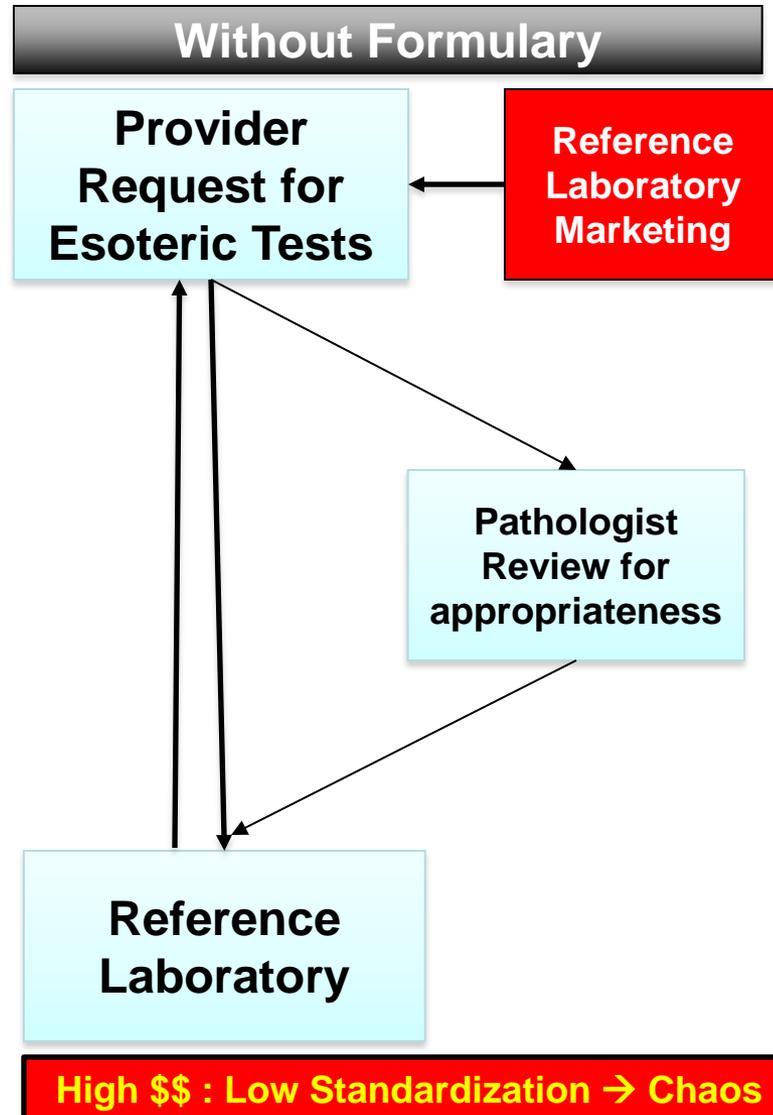
Cost savings associated with LOS



- Average reduction LOS = 4.78 days
- Average reduction Costs/LOS = \$19,822.66 per Candida sepsis episode
- **Projected annualized LOS cost savings = \$1,110,069.00**
- **Plus annual lab savings = \$1,225,069.00**



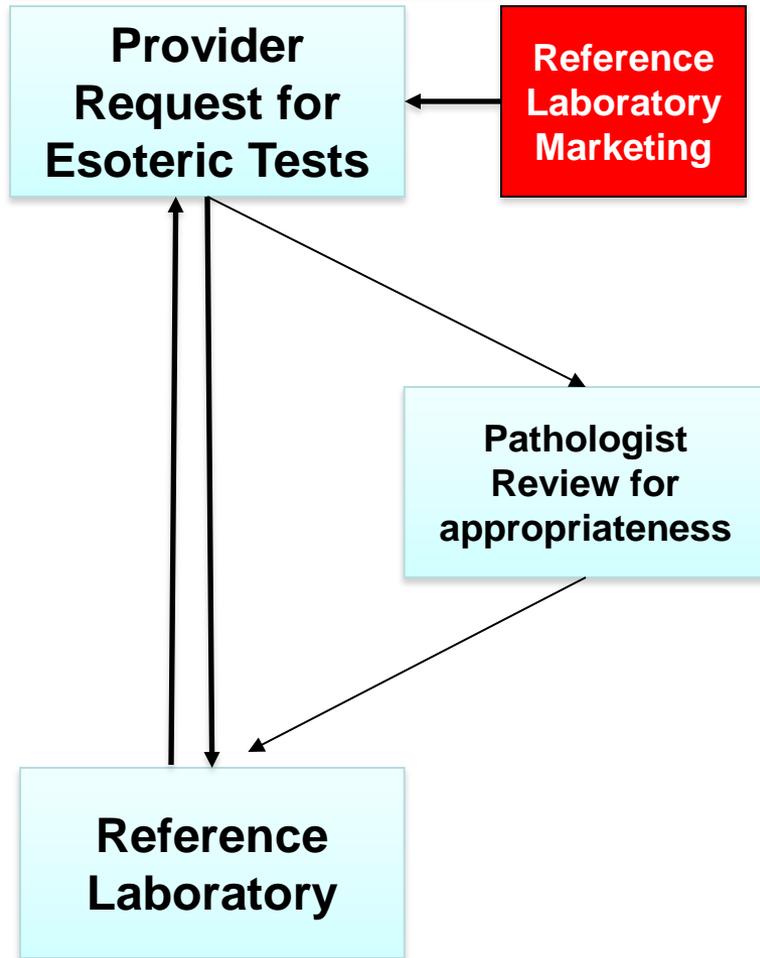
Test Utilization Management





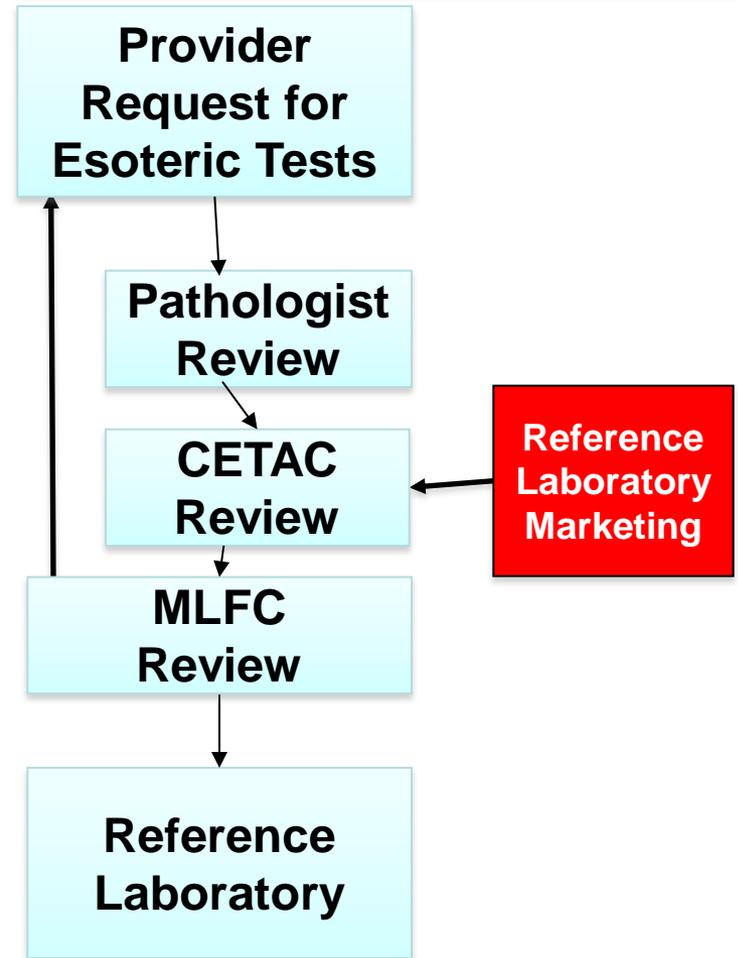
Test Utilization Management

Without Formulary



High \$\$: Low Standardization → Chaos

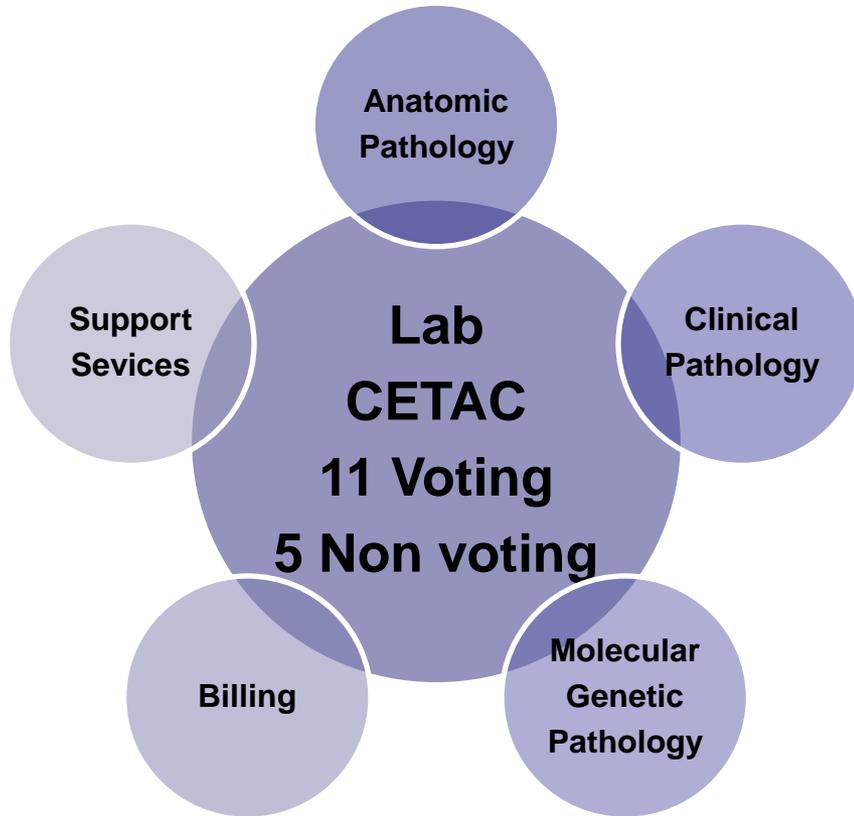
With Formulary



Low \$\$: Standardization → Better Utilization



Test Utilization Management



28 Tests [\$85 - \$5800]

2 Unrestricted [\$55-\$140]

19 Restricted [\$84-\$2500]

7 Not Available [\$93-\$5800]

Receive New Test Service Request



Identify Leads: Pathology & Clinician



Gather Information on Lab and Charges



Medical and Financial Impact Analysis



Discuss at CETAC Meeting, make determination



Memorandum and notification to Med. Lab Formulary Committee



Test Utilization Management

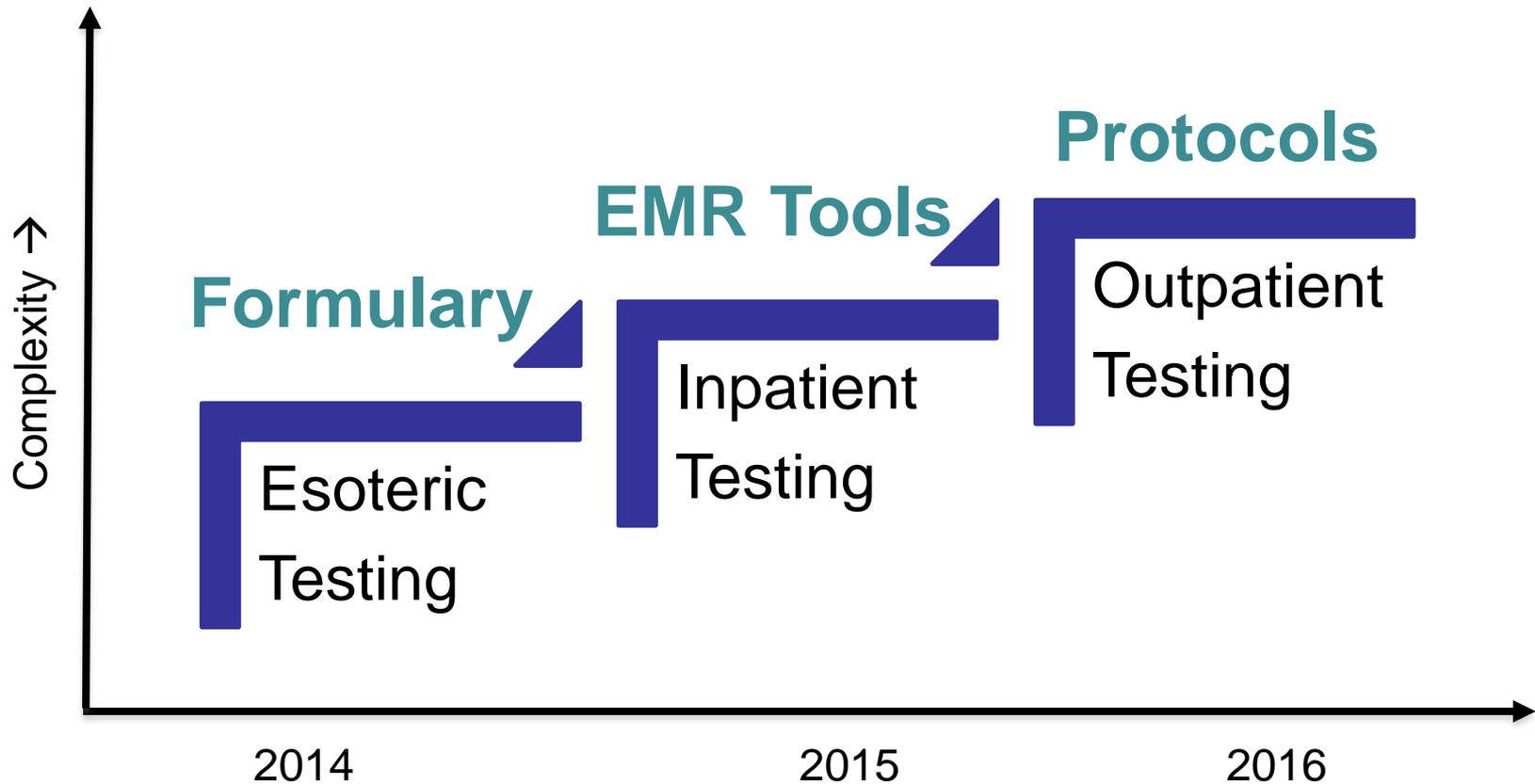
Cost-Avoidance

| Test | Vendor Claim | CETAC Determination | Cost and Reimbursement | Potential Cost Avoidance |
|---------|---|---|--|--|
| Assay 1 | A genomic profile that helps physicians make treatment decisions. | NOT AVAILABLE Reasons: -No FDA approval -Not in NCCN guidelines -Not for HFHS Trials | Cost: \$5800 and \$7500 Reimbursement: \$0 LOSS: \$5800-\$7500/test | >\$10 million/year In HFHS, 2000 cases/year will qualify for 'genomic testing for potential targets'. This will be in addition to routine pathological diagnostic work-up. |
| Assay 2 | Quantitative assessment of the likelihood of distant recurrence in patients diagnosed with ER+ node-negative breast cancer. | NOT AVAILABLE Reasons: -No FDA approval -Not in NCCN guidelines | Cost: \$3500 Reimbursement \$150 LOSS: \$3350/test | > \$3.5 million > 300 cases/y of breast carcinoma are diagnosed in HFHS. A cohort of >1000 patients may qualify per vendor claim. |
| Assay 3 | Aid in the classification of the tissue of origin and tumor subtype in conjunction with standard clinical and pathological assessment by a qualified physician. | NOT AVAILABLE Reasons: - No FDA approval - Not in NCCN guidelines | Cost: \$4750 Reimbursement: \$0 LOSS: \$4750/test | >\$1.4 million/year Per vendor claim, test is to be used in 30 % of metastatic cases that remain unclear. If we assume 30% malignancies are metastatic at diagnosis then HFHS has 300 cases/y (i.e. 10% of the total 3000) that may qualify per vendor criteria. |
| Assay 4 | Tests for *** protein and **** may be used as <u>supplemental</u> tests to help establish a diagnosis of Alzheimer Disease. | NOT AVAILABLE Reasons: - No FDA approval - Not required for diagnosis | Cost: \$1160 Reimbursement: \$52 LOSS: \$1108/test | >\$110,000/year Per clinical expert, the utilization of this test is expected to be around 100 cases/year. |



Test Utilization Management

The Path Forward....





Value of Clinical Consultant

**What pathologists
bring to the table....**

**Physician who can
interface with other
physicians**

**Understands the
medical implications
and technical
limitations**

**Can suggest and
provide rationale for
alternative testing
modalities**

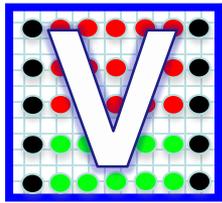


**What pathologists
need from the
administration....**

**Medical laboratory has
to be visible and
involved in decision
making**

**A mechanism must
exist for interaction and
exchange of
information**

**Must be recognized
and incentivized for
improving lab
utilization**



Value Metrics

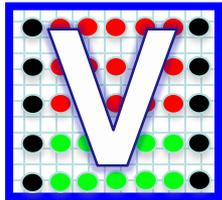
Won't always be cost and productivity but....

**Downstream episode of care
efficiencies and clinical outcomes**

Relating to Value Metrics

The language of the hospital C-Suite

- Risk Adjusted LOS (case type and severity)
- Emergency Room LOS
- Case Mix Adjusted Episode Costs
- Risk Adjusted Early Readmission Rate
- Average Time Emergency Department (ED) Door to Bed Average Time
- ED Treatment to Release
- Divert Hours for ED
- Pharmacy cost/DRG
- RVUs/DRG
- Cost per unit of service
- Salary Expense per Adjusted Patient Day
- Full Time Equivalent (FTE) per Adjusted Patient Day
- Supply Expense per Adjusted Patient Day



Are You Ready to Unleash the Power of Pathology's V-Man?





*“Improved efficiency is only meaningful when it leads to **cost reduction**. This requires producing the required amount with the least resource.”*

*“Efficiency improvement must be looked at not only at the level of individual people, lines staffed by teams of people, and groups of these lines but as efficiency of the **entire system**.”*

-Taiichi Ohno