When Your Hospital CFO Asks: How We Show Our Lab's Gains from ISO 15189 And QMS Programs

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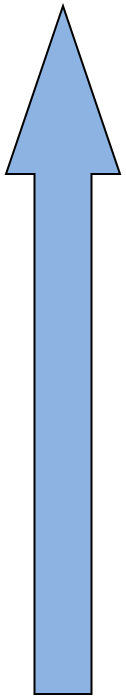
Lab Quality Confab

Stages of Quality



Stage	Activities Performed
Total Quality Management	Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction
Quality Cost Management	Management system for the economic aspects of the "cost of quality"
Quality Management System	Systematic process-oriented approach to meeting quality objectives
Quality Assurance	Planned and systematic activities to provide confidence that an organization fulfills requirements for quality
Quality Control	Operational process control techniques to fulfill quality requirements for regulatory compliance and accreditation

Source: CLSI QMS-20

Stages of Quality – Adoption in Medical Laboratories

Years	Stage	Quality Progress
1970s-1980s	QC QA	1977 – Westgard publications on QC 70s/80s – American "Quality Awakening" • Deming and Juran influence American business to respond to Japanese competition • QA principles are applied to laboratory
1990s – 2000s	QMS	Early 90's – rising popularity of ISO 9001 - General QMS requirements 1999 – CLSI develops GP-26 - QMS guidelines for medical labs 2003 – ISO 15189 - QMS requirements for medical labs
2010s	CoQ	2014 – CLSI develops QMS-20 - guidelines for measuring quality costs

Avera McKennan Hospital & University Health Center – Our health system footprint

Avera McKennan Region & Avera McKennan Hospital

- Largest region of Avera Health
  - Large 545-bed tertiary hospital, 13 regional hospitals, 58 primary and 27 specialty care clinics
  - Heart hospital, behavioral health hospital, children's hospital, cancer institute, transplant institute, neuroscience institute, research & genomics institute
  - Approx 6,000 FTEs
  - 1.3 million patient visits

Avera McKennan Hospital & University Health Center – Our laboratory footprint

- Employees (122.3 FTE's)
  - 64.6 technical
  - 57.7 non-technical/support staff
- Testing specialties
  - Routine clinical specialties
  - Virology
  - Molecular diagnostic
  - Flow cytometry
  - HLA
  - Blood donor and procurement service
- Reference laboratory service line
  - 200+ outreach clients (SD, MN, IA)

Avera McKennan Hospital & University Health Center – Our laboratory footprint

- Testing volume FY13
  - Inpatient and outpatient – 1,056,000
  - Reference laboratory – 548,000
- Revenue FY13
  - Inpatient and outpatient – $114 mil
  - Reference laboratory - $8.5 mil
- Accreditations

CAP	AABB	FACT	UNOS
CAP 15189	FDA (regulated)		(ASHI-2015)

Avera McKennan Hospital & University Health Center – Our quality journey

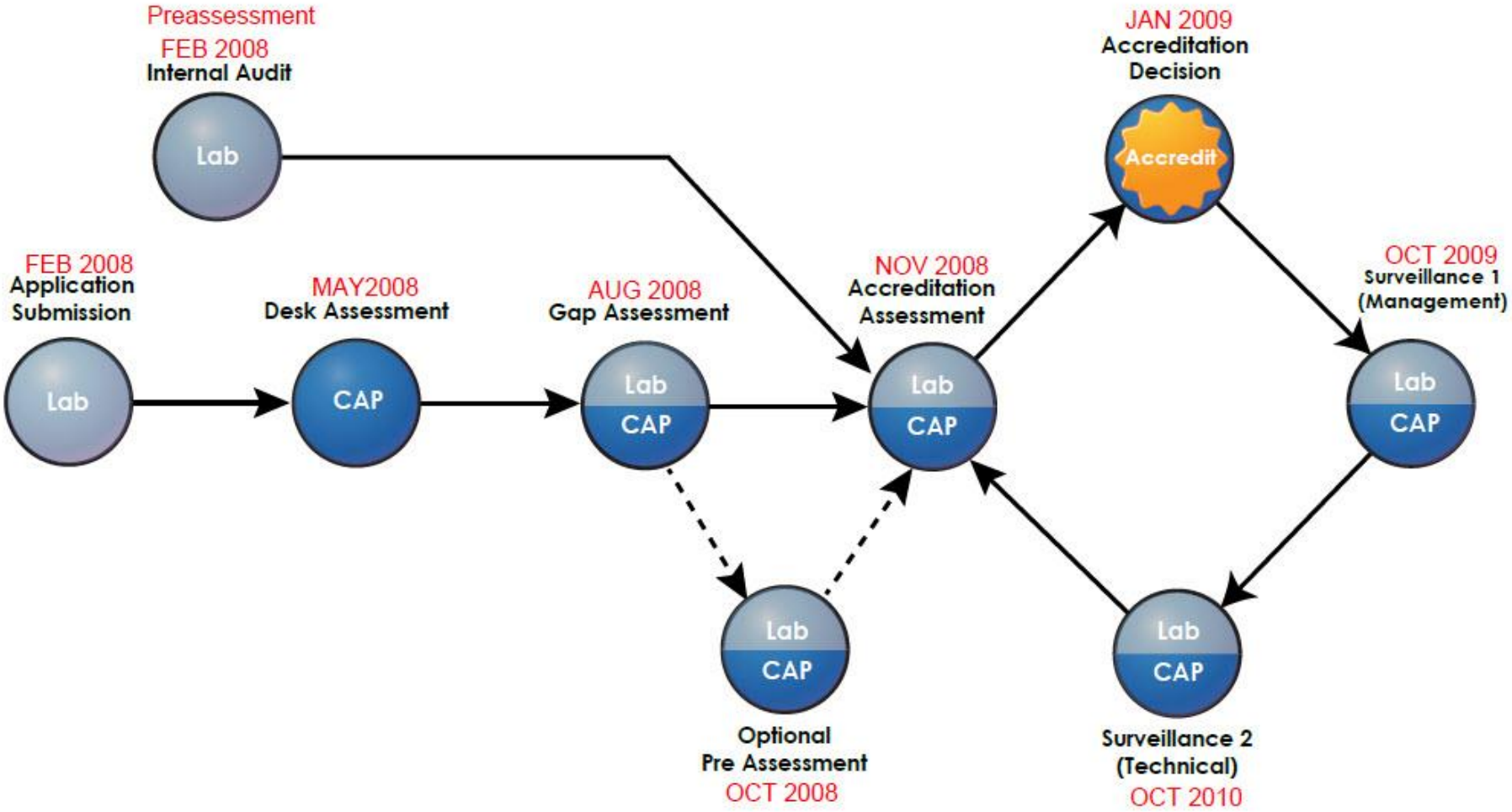
- CAP Laboratory Accreditation and AABB
- LEAN – April 2004
  - Core lab, client service department, moved from main hospital to another location on campus, decreased staffing by 10+%
- CAP 15189SM (ISO 15189) – January 2009
  - 2nd Medical Laboratory in U.S.
  - 1st Hospital Medical & Anatomic Pathology Laboratory in U.S.
  - 2nd reaccreditation assessment Oct. 2014 (added HLA)
  - Current longest accredited CAP 15189 Laboratory in the U.S.

Avera McKennan Hospital & University Health Center – Our objectives

- Raise the bar on service and quality excellence for all patients and customers
- Enhance and assure an effective quality management system (QMS)
- Increase on our gains from LEAN
- Extend laboratory quality initiatives outside normal laboratory boundaries
- Engage staff in the quality process

Avera McKennan Hospital & University Health Center – Our ISO 15189 journey

- **Our timeline and time investment**
  - Quality manager hired – January 2008



Avera McKennan Hospital & University Health Center – Our recognized value of the changes

- Improved controls and management review
- Documented employee engagement and ownership
- Increased knowledge of program effectiveness and efficiency
- Enhanced continuous quality improvement
- Achieved impacts outside our normal boundaries
- Recognized financial benefits

Avera McKennan Hospital & University Health Center – Value of ISO 15189 from the AVP's view

- Inspection Readiness
- Role in standardization of processes
- Prestige

Avera McKennan Hospital & University Health Center – Value of ISO 15189 from the AVP's view

- Inspection Readiness
  - 3 inspections completed in 9 days
    - FDA (unannounced) September 30 – October 3
    - CAP 15189 reaccreditation October 7 – 9
    - CAP LAP Interim inspection October 10
  - Confidence expressed by our Regional President/CEO to our 2013 CAP LAP inspection team

"the lab is the one department I don't worry about"

-Dave Kapaska, DO

Avera McKennan Hospital & University Health Center – Value of ISO 15189 from the AVP's view

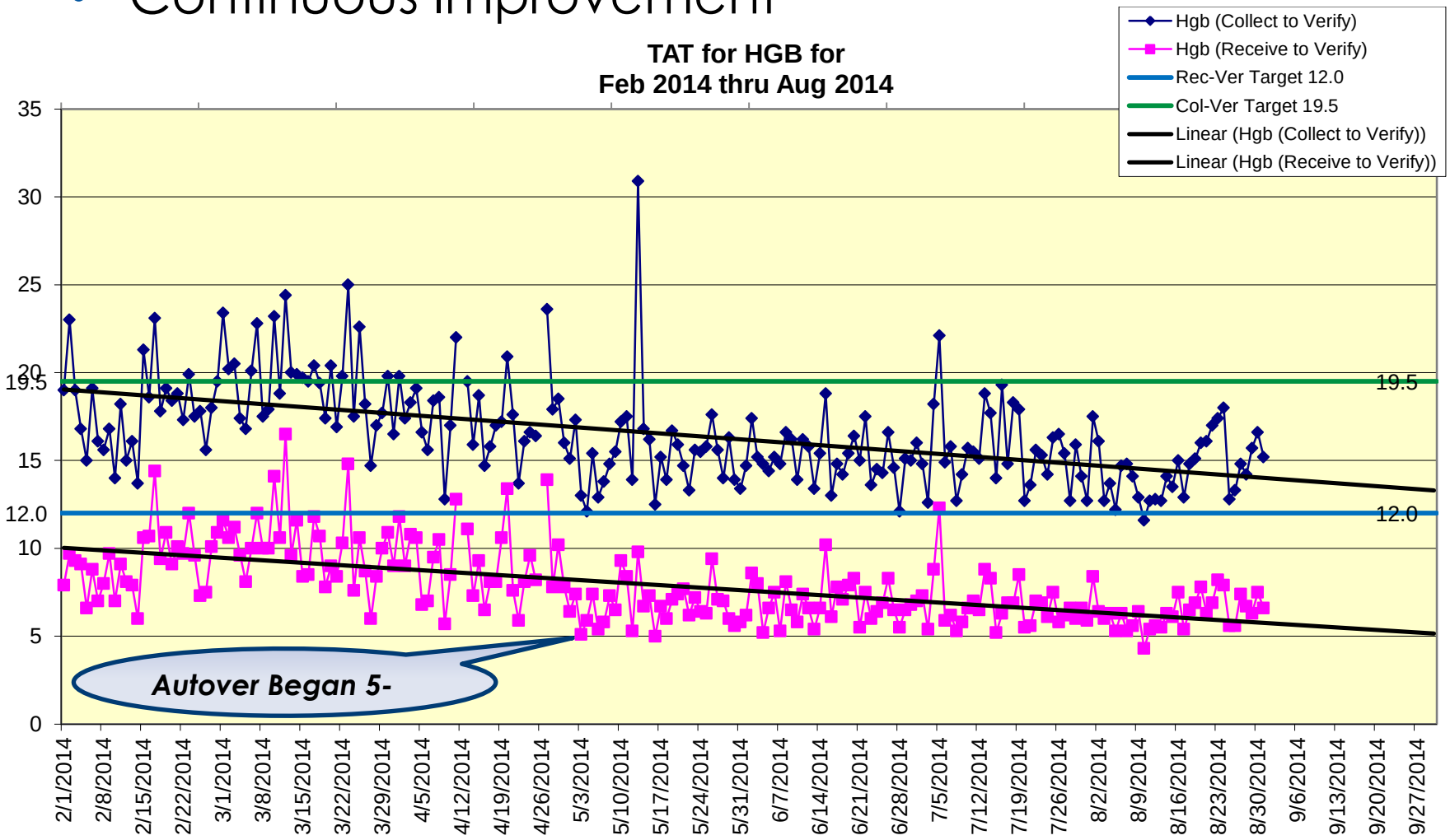
- Role in standardization of processes
  - Use of process flow charts & root cause analysis
    - Going beyond Lean use of process charting to now using for financial aspect
  - Push-back to vendors ($100,000's in savings)
    - Example – one test sent to referral lab, worked with sales representative to decrease cost of that test from $2300 to $500 for cost savings of $56,000 per year
    - ISO 15189 has increased our confidence level and prestige in organization
    - Genetic billing – look at expense for patient as well as for Avera McKennan. We know we are doing the right thing for our patients.

Avera McKennan Hospital & University Health Center – Value of ISO 15189 from the AVP's view

- Prestige
  - Increased market share in competitive market
  - Recognition locally, regionally, nationally
    - Farming community as well as manufacturing familiar with ISO 9001 and recognize significance of ISO achievement
  - Influence on grant procurement & provision of insurance
    - Research branches
    - Avera Health Plans

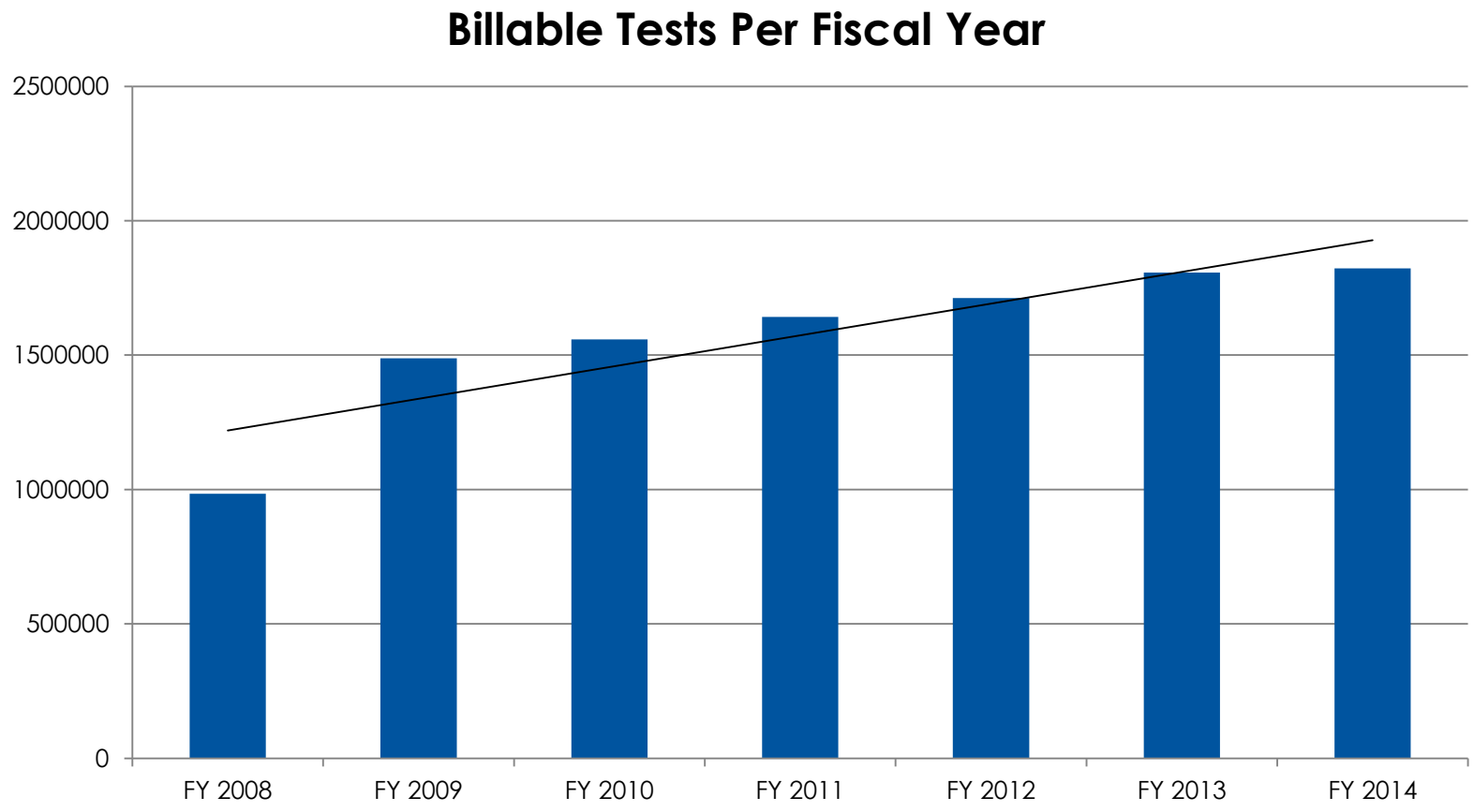
"Sell" to Executive Level (and fend off adding satellite labs - Cancer Institute, ED, etc.)

- Continuous Improvement



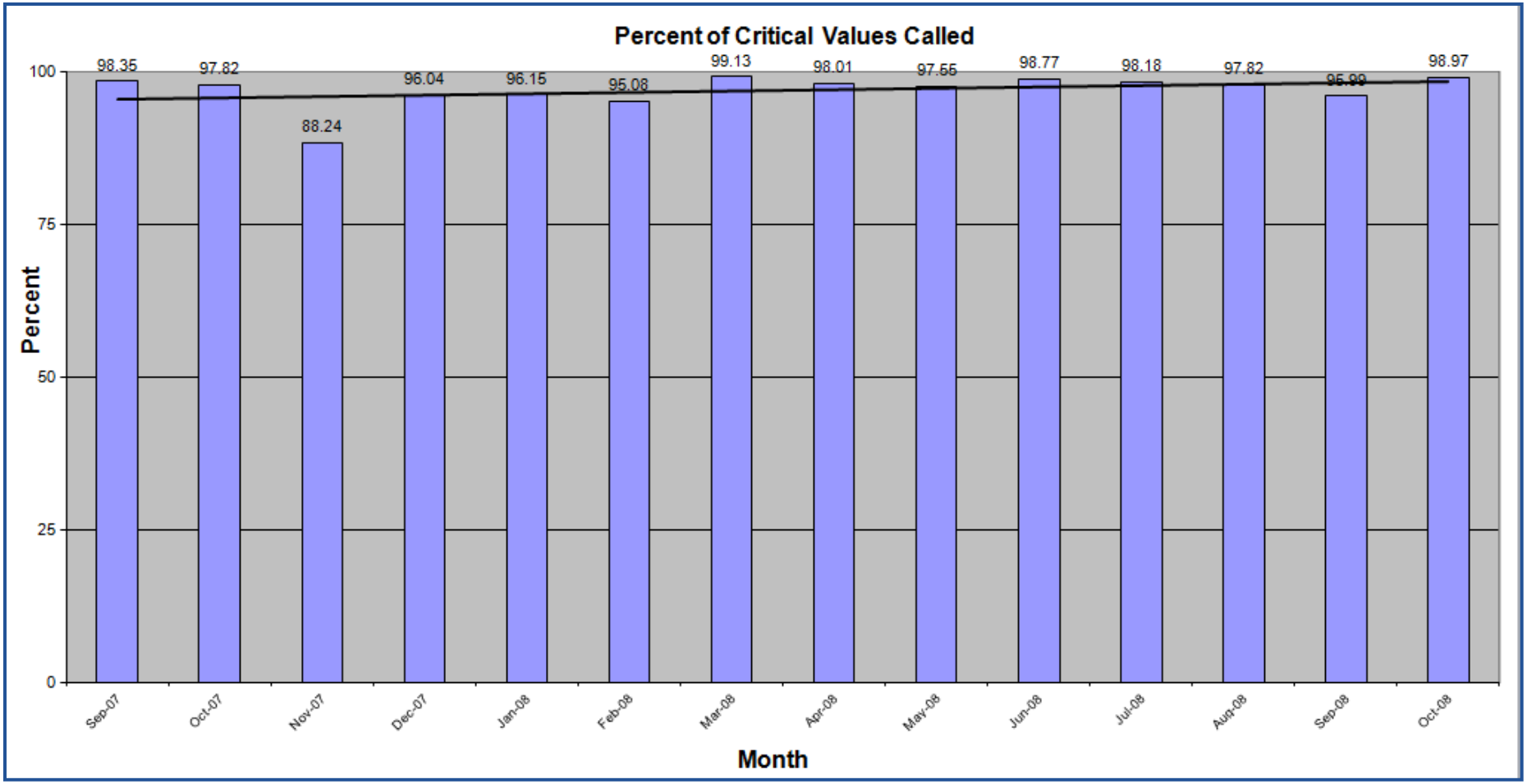
“Sell” to Executive Level

- Test Volumes/Billables Steady Increase



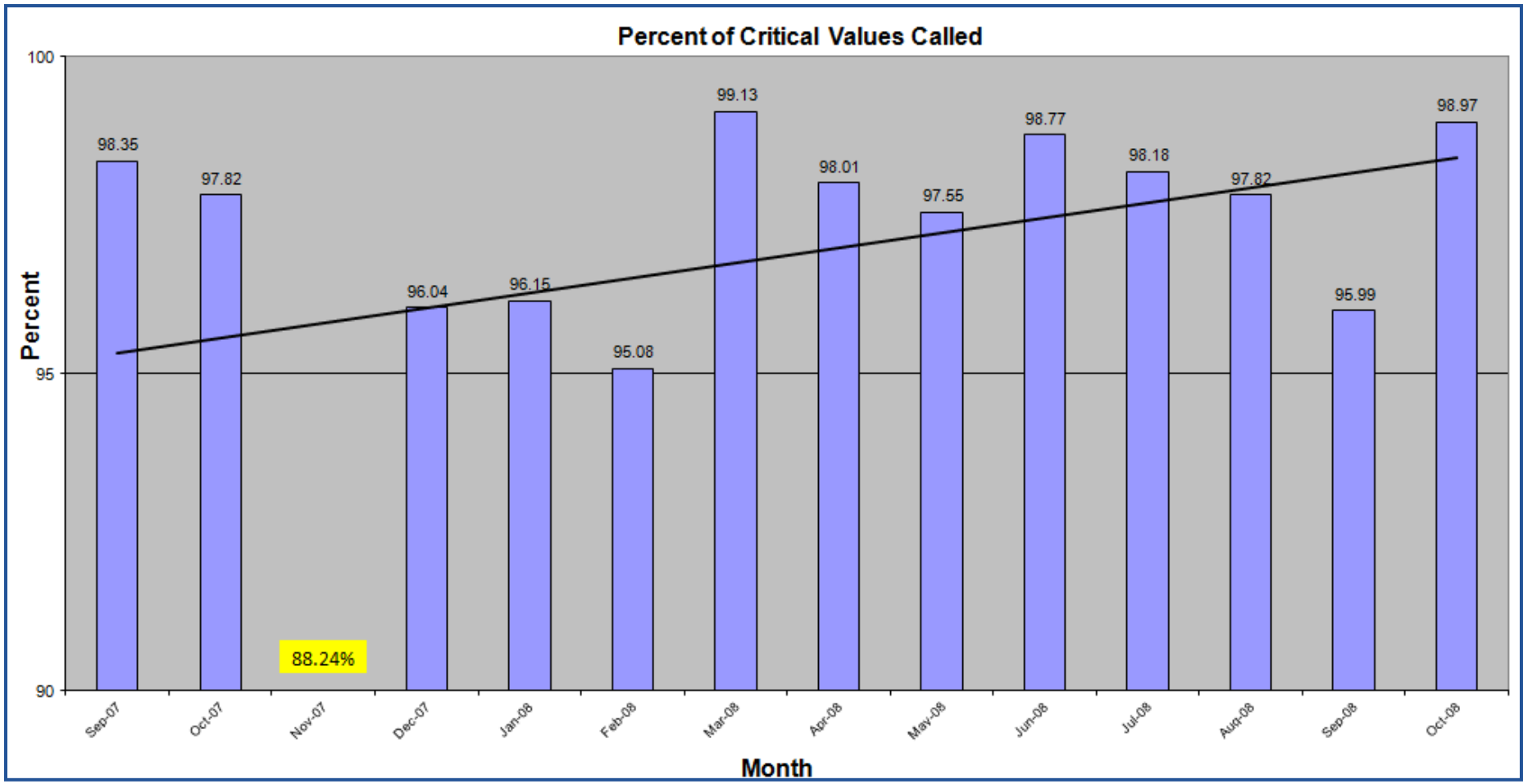
Critical Values – To Continuously Improve Change the View

- Prior to ISO – Critical Value monitoring



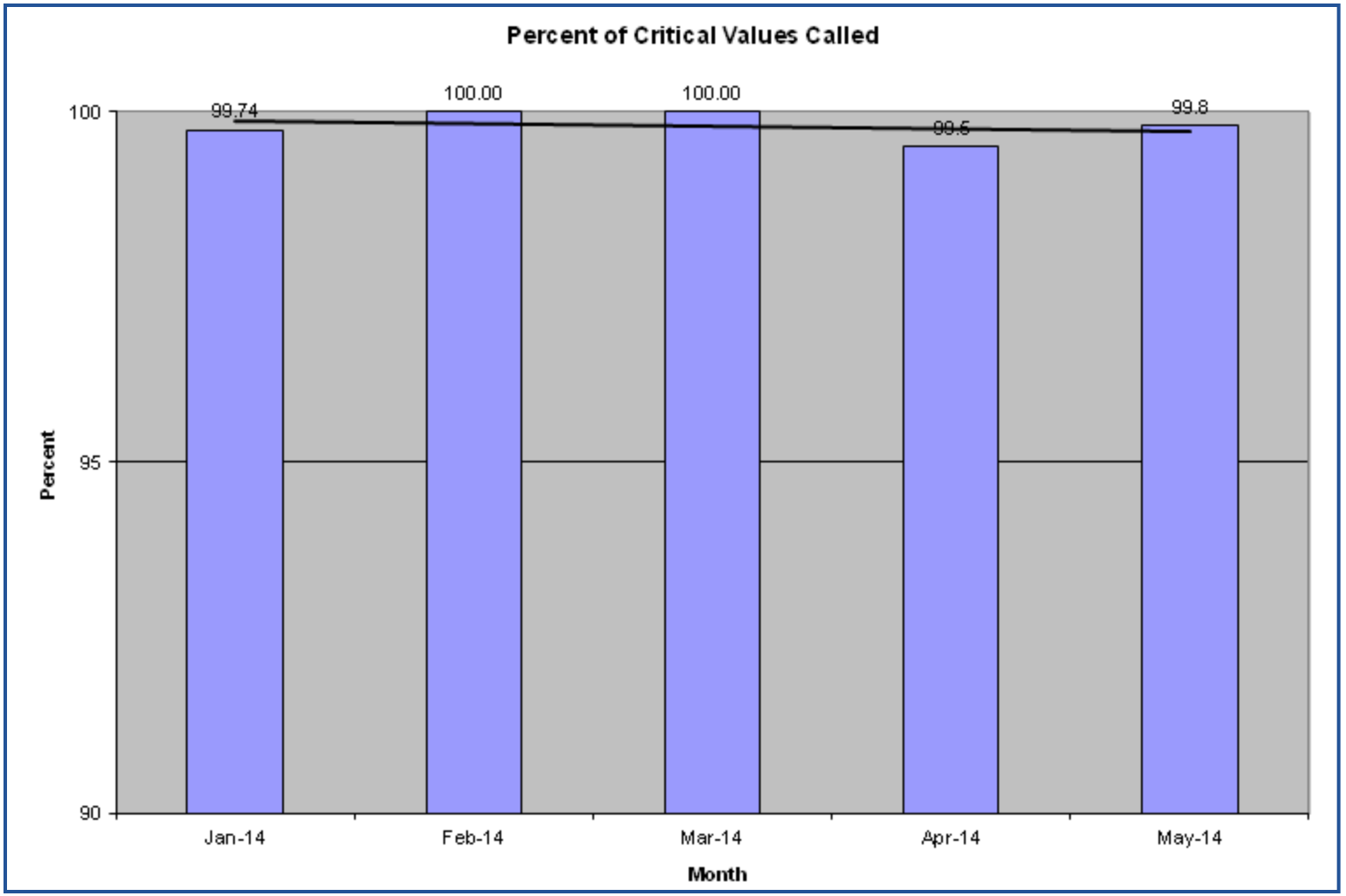
Critical Values – To Continuously Improve Change the View

- After ISO Assessment – Changed the view to push towards continuous improvement



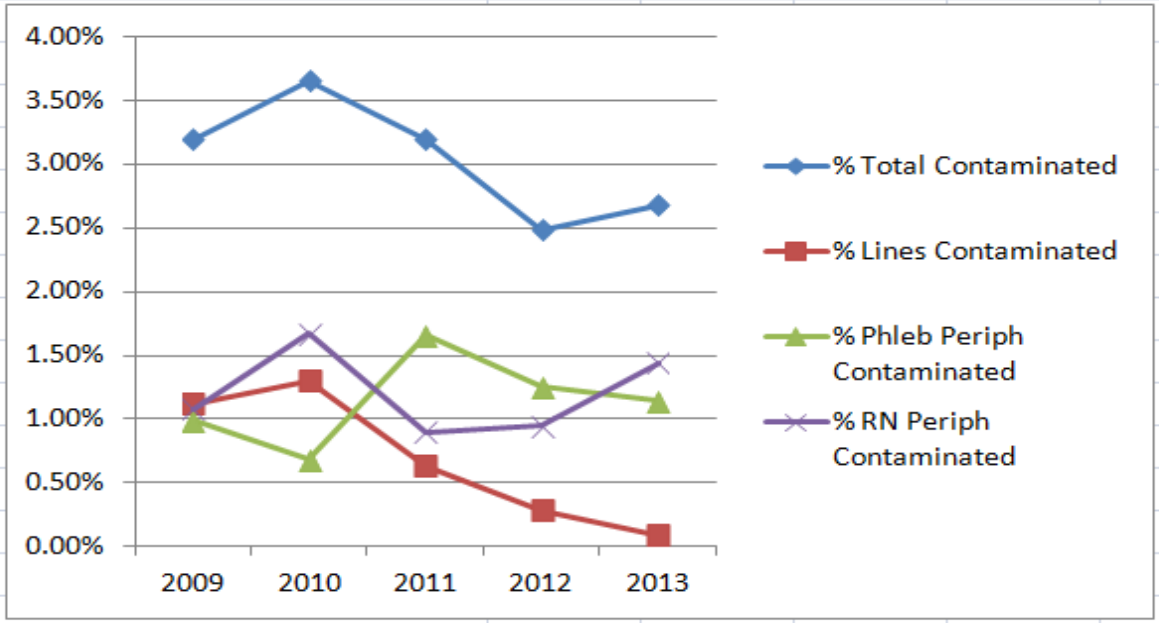
Critical Values – To Continuously Improve Change the View

- 2014 – After auditing and CQI actions



Blood Culture – Contamination Prevention

	2009**	2010	2011	2012	2013
Total BC*	8489	11464	10011	10093	9227
Total Line Draws				1817	597
Total Peripheral Draws				8276	8630
Line Draws Contaminated	95	149	63	26	8
Lab Phlebotomy Draws Contaminated	84	79	166	122	105
RN Phlebotomy Draws Contaminated	92	191	90	91	133
	2009	2010	2011	2012	2013
% Total Contaminated	3.19%	3.65%	3.19%	2.48%	2.67%
% Lines Contaminated	1.12%	1.30%	0.63%	0.28%	0.09%
% Phleb Periph Contaminated	0.99%	0.68%	1.66%	1.25%	1.14%
% RN Periph Contaminated	1.08%	1.67%	0.90%	0.95%	1.44%



*Total Blood Cultures Ordered. Could include 1 (ex. Pediatric) or 2 (Aerobic & Anaerobic.) BC counted as contaminated if even on bottle contaminated.

**2009 represents 11 months of data.

Blood Culture – Contamination Prevention

- Continuous improvement through assessment, actions and feedback!
  - 2010 – Contamination rates exceeded <3.0 ASM/<2.5 CAP
    - QA Committee and Infectious Disease specialty reviews and recommendation = CQI initiative to decrease contamination rates
  - 2010-2011 – hospital initiative to eliminate collection through lines (rate 3.65 →3.19)
  - 2012 – additional CQI actions taken (rate 3.19→2.48)
    - Staff training, purchased webinar, implemented specific orientation/training for new employees
    - Implemented rate tracking and employee feedback for individuals

What are the financial benefits? We can use an example...

- What are the consequences of blood culture contamination ?

Article	Mean difference in length of stay	Difference in median total costs
Clinical and economic impact of contaminated blood cultures within the hospital setting *Journal of Hospital Infection, 2011* [2] (study conducted in Ireland)	5.4 days	$2,513
Contaminant blood cultures and resource utilization. The true consequences of false-positive results *JAMA, 1991* [3] (study conducted in Boston)	4.5 days	$4,385

This is the "cost of quality"

- Laboratory expenses can be initially divided into two areas.
  - The expenses of running the lab without errors, retesting, or any mistakes.
  - Expenses that involve mistakes, attempting to prevent mistakes, and dealing with the consequences of mistakes.

The value of cost of quality measures

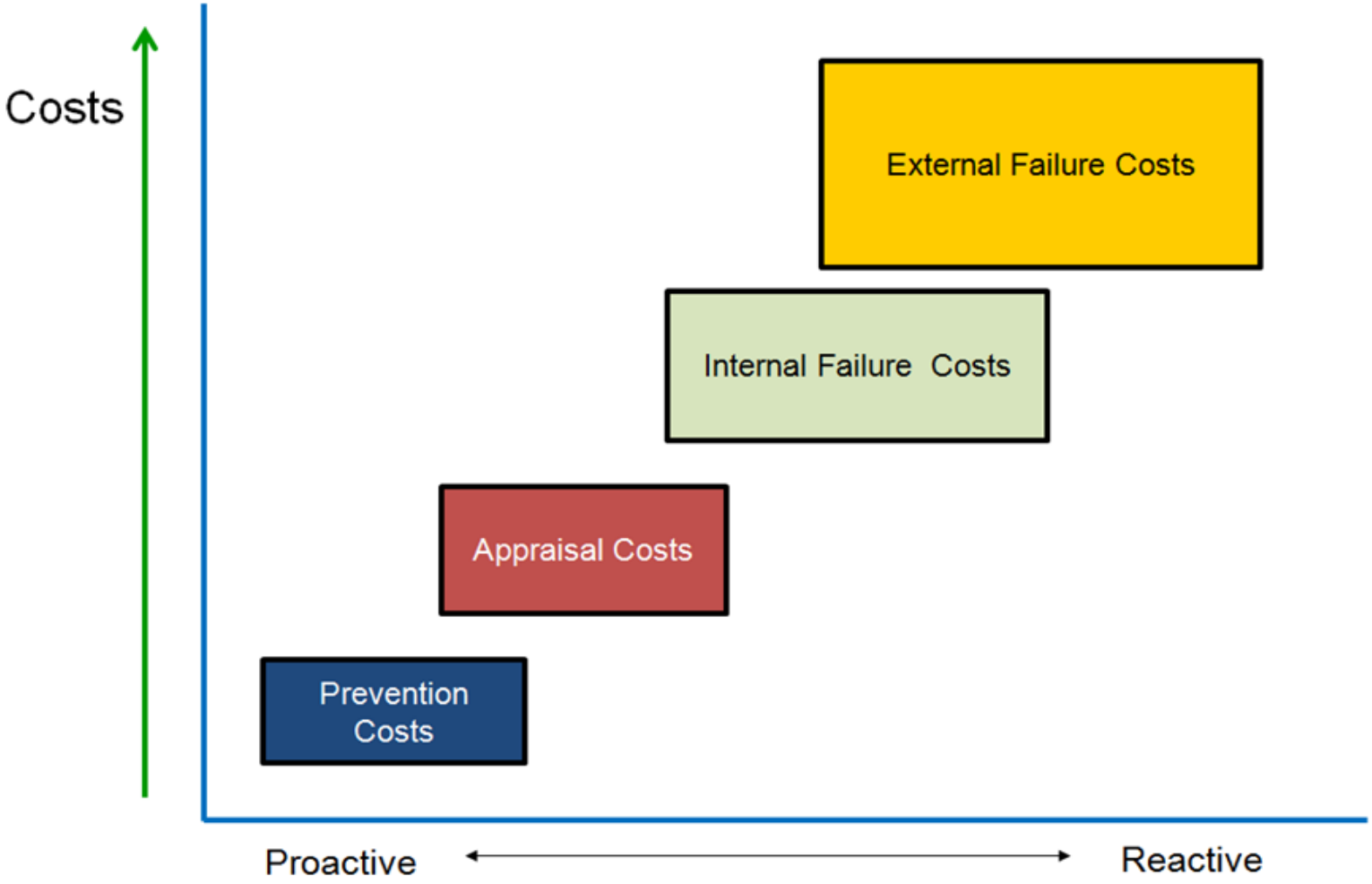
"A properly understood and managed quality cost system will aid organizations in realizing costs savings while avoiding some of the serious pitfalls that can accompany cost cutting: decreases in product or service quality, increased customer dissatisfaction, added rework costs, or simple shifts in costs from one area to another."

From Douglas C. Wood. *The Executive Guide to Understanding and Implementing Quality Cost Programs*. ASQ Quality Press, 2007

The expenses beyond 'no errors' can be redefined as:

- **Prevention expenses** are from proactive measures to improve quality and prevent errors throughout the laboratory.
- **Appraisal expenses** are from inspection and maintenance.
- **Internal Failure expenses** occur when something has gone wrong with the process.
- **External Failure expenses** occur when results have left the laboratory and failed to meet the requirements of customers for whatever reason.

Proportions of quality costs



Applying the model – quality costs associated with blood culture contamination

- **Prevention Costs:**
  - Creating/ maintaining systems of control for blood culture contamination
- **Appraisal Costs:**
  - Management audits
  - Data collection
  - Process reviews

Applying the model – quality costs associated with blood culture contamination (continued)

- **Internal Failure Costs:**
  - Additional supplies
  - Phlebotomist time, accessioning time
  - Culturing time, Gram stains & interpretation for retests
- **External Failure Costs:**
  - Increased length of stay, increased physician time to deal with individual cases
  - Consequences of patients not being diagnosed in a timely way, or misdiagnosed

Annual quality costs

Category	Before	1st year	2nd year
Prevention	$0	$809	$650
Appraisal	$816	$816	$1128
Int. Failure	$7245	$6210	$5175
Ext. Failure	$642,000	$550,000	$459,000
Total	$649,000	$557,000	$466,000

Example calculation formulas (Before)

Internal failure:

- Lab tests to work up contaminated blood culture
  - $14 per test x 9000 tests per year x 0.035 contamination rate
  - $4410
- Redraw/Repeat Blood culture
  - $9 per test x 9000 tests per year x 0.035 contamination rate x 0.2 redraw rate
  - $567

External failure:

- Added length of stay
  - 9000 tests per year / 2.5 tests per patient = 3600 patients
- Added pharmaceuticals

Example calculation formulas (Before)

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  - $567

External failure:

- Added length of stay
  - 9000 tests per year / 2.5 tests per patient = 3600 patients
  - 3600 patients x 0.035 contamination rate = 126 affected patients
- Added pharmaceuticals

Example calculation formulas (Before)

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External failure:

- Added length of stay
  - 9000 tests per year / 2.5 tests per patient = 3600 patients
  - 126 affected patients x 4.5 days per patient = 567 annual extra patient days
  - 567 annual extra patient days x $1000 per day = $ 567,000 Cost
- Added pharmaceuticals

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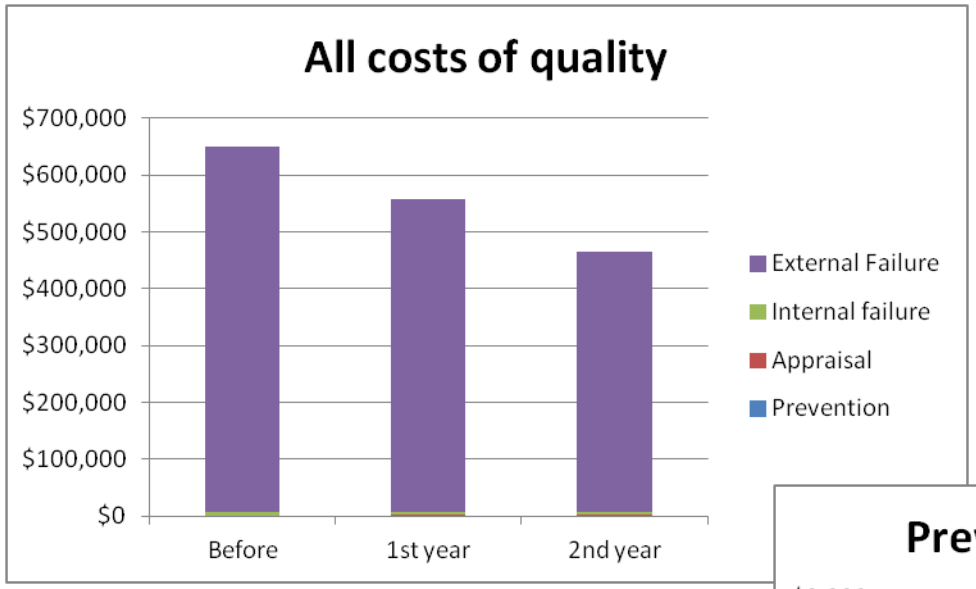
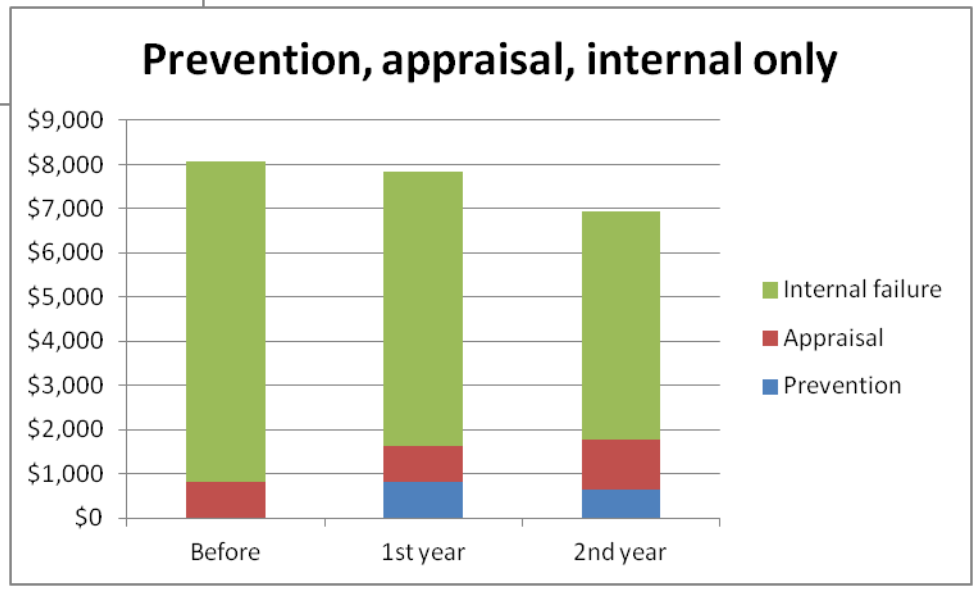
  - 126 affected patients x 4.5 days per patient = 567 annual extra patient days
  - 567 annual extra patient days x $1000 per day = $ 567,000 Cost
- Added pharmaceuticals
  - 3600 patients x 0.035 contamination rate x $600 per day cost
  - $75,600 Cost

Annual quality costs: charts





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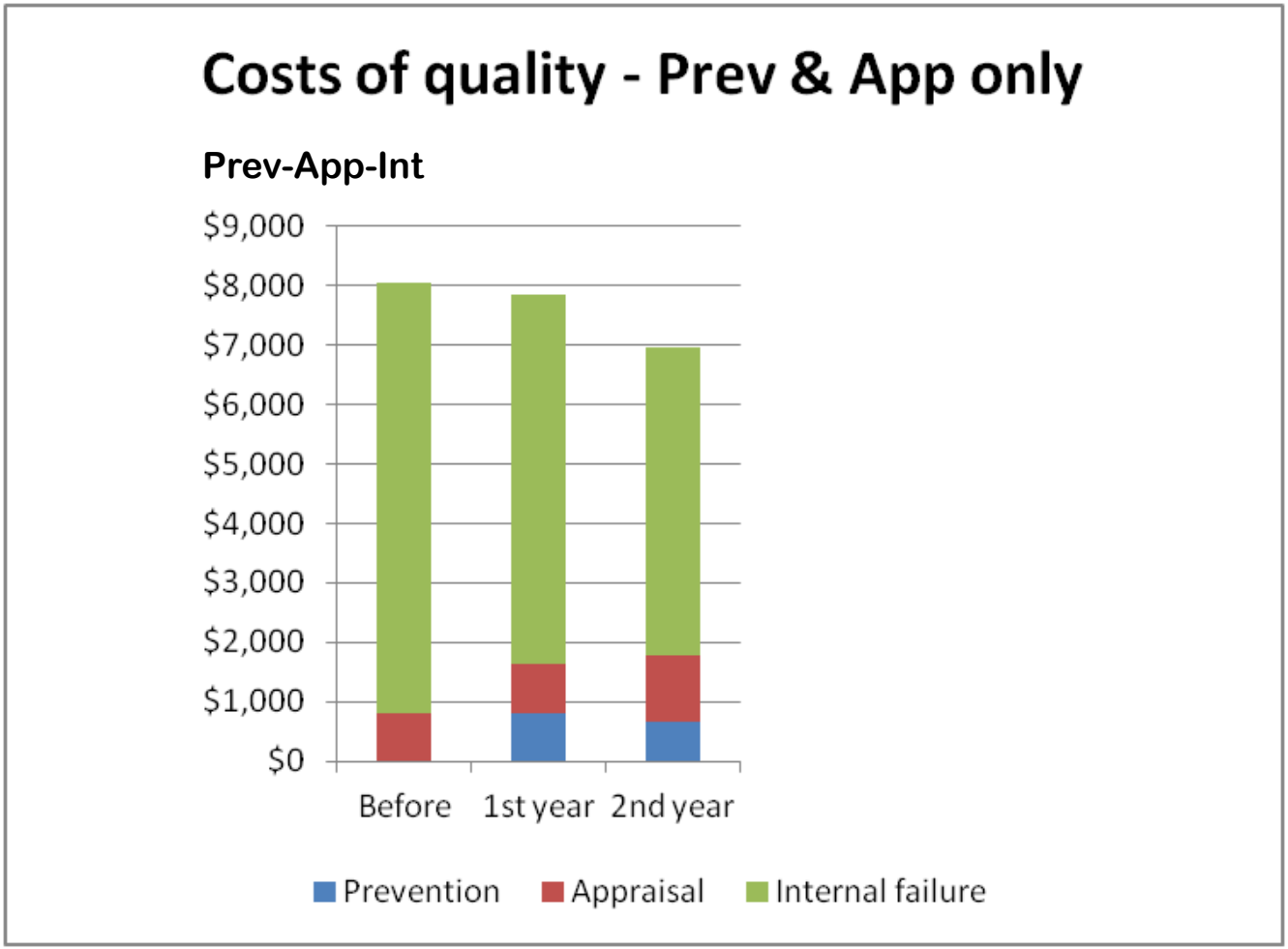
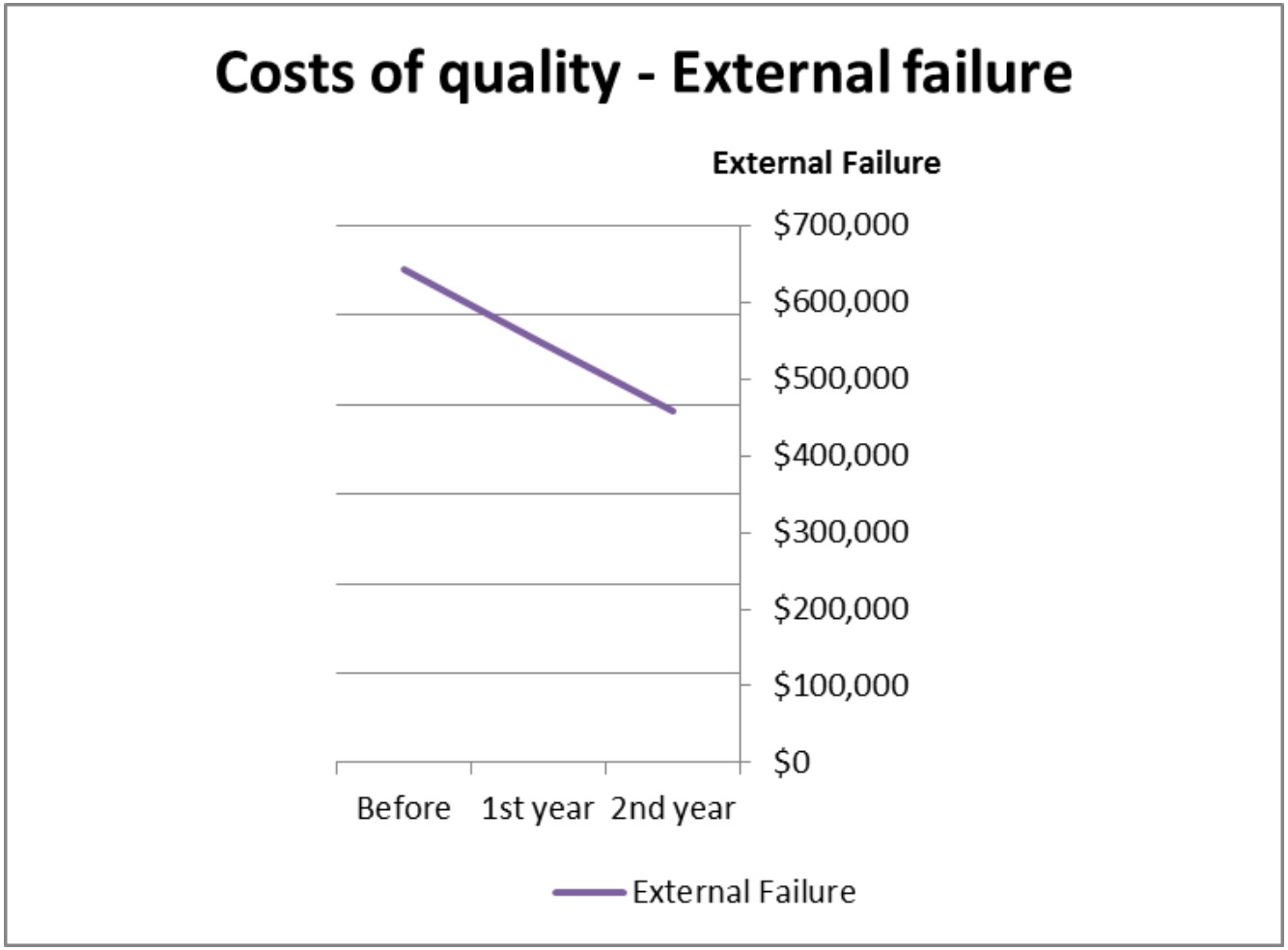


Annual quality costs: charts



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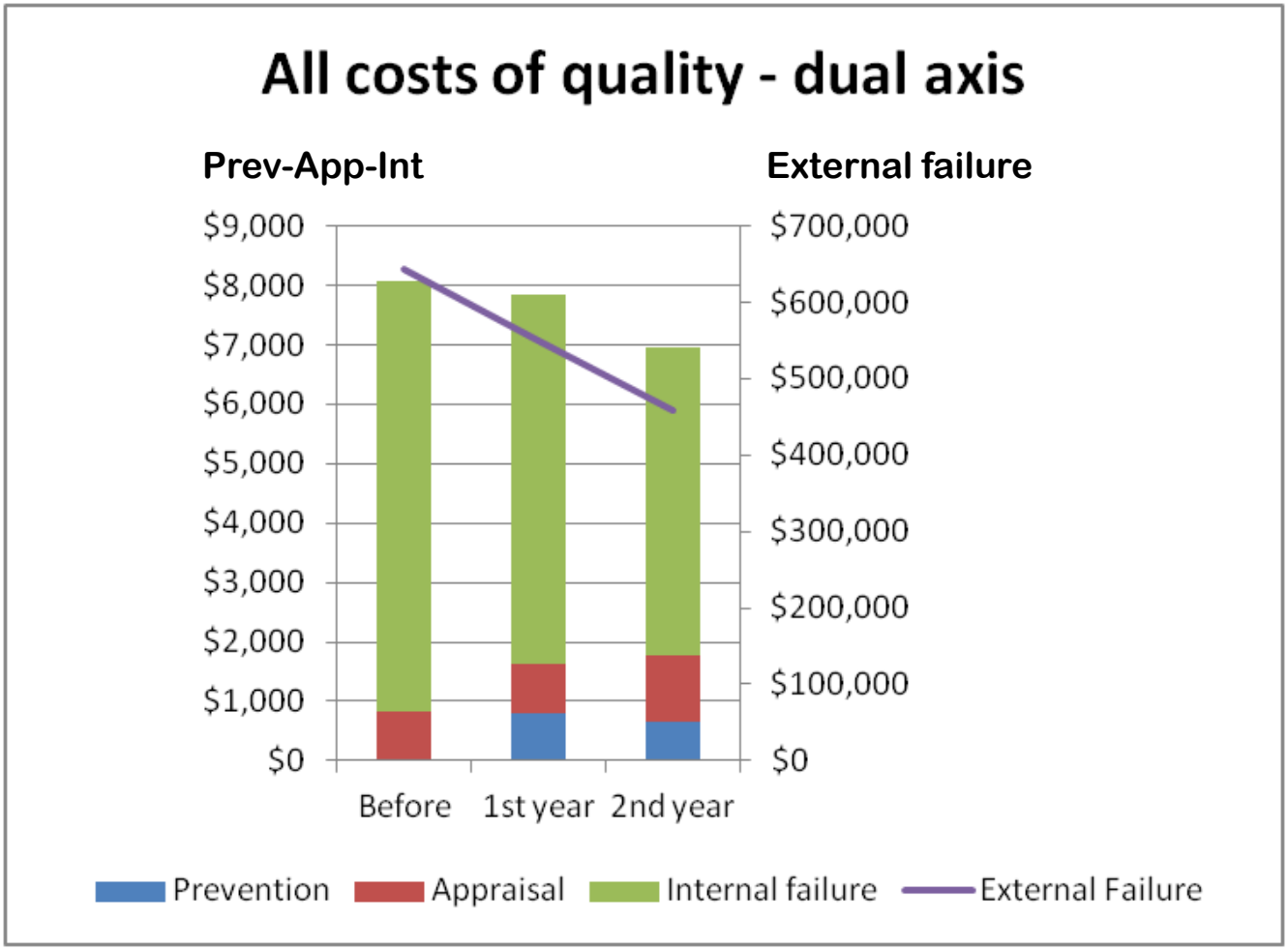
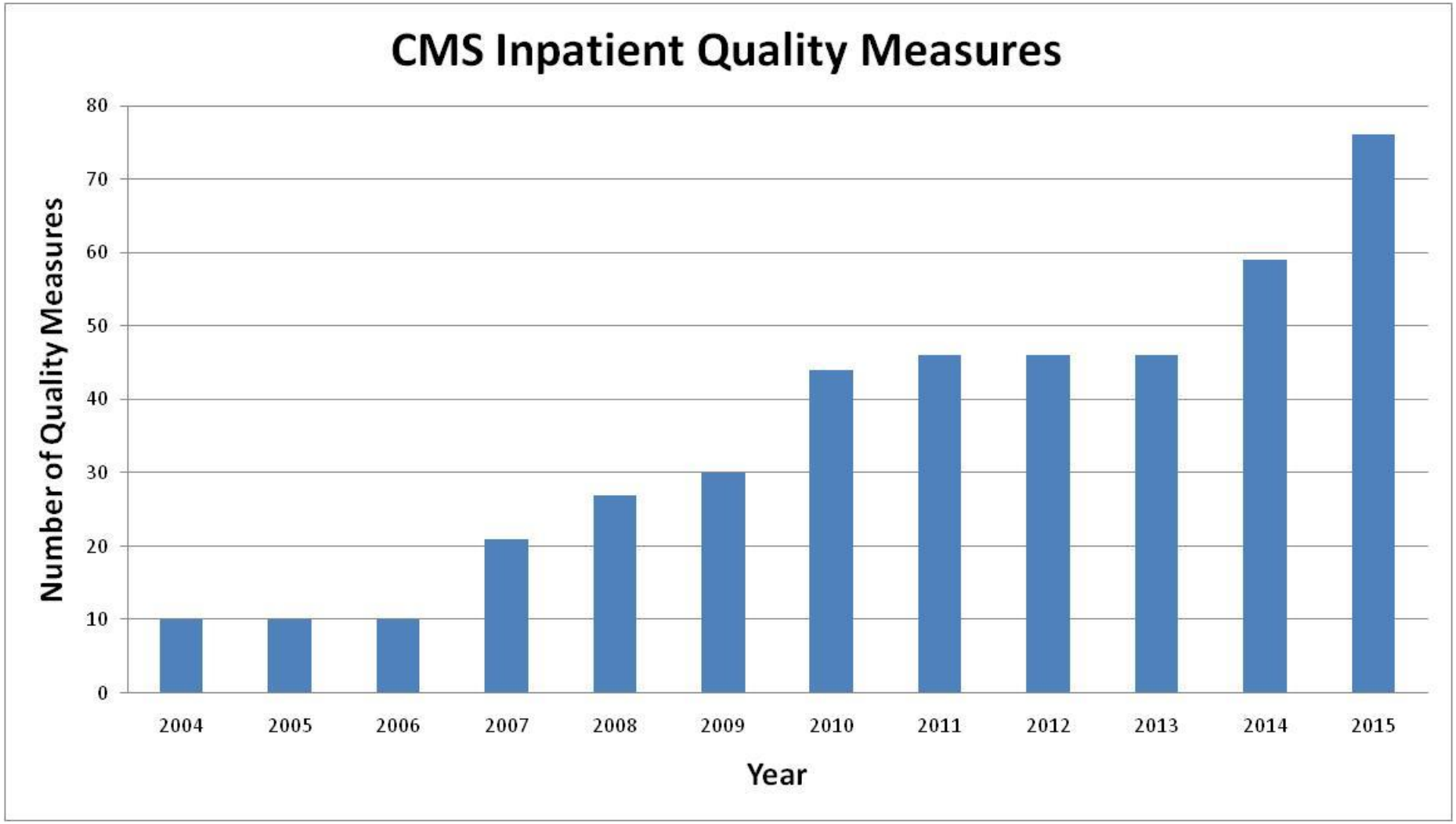


CMS Emphasis on Quality – Inpatient Services

- Section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA)
  - 0.4% reduction to inpatient payments beginning in 2005 for non-reporting hospitals
- Section 5001(a) of the Deficit Reduction Act of 2005 (DRA)
  - Increase reduction to 2.0% beginning in 2007 for non-reporting hospitals

CMS Quality Measures



CMS Emphasis on Quality – Outpatient Services

- Tax Relief and Healthcare Act of 2006
  - 2.0% reduction to outpatient payments beginning January 1, 2009 for non-reporting hospitals
- Similar to the inpatient quality reporting
- Began with the reporting of 7 quality measures versus 10 inpatient measures
- Expanded measures beginning in 2011
- 23 quality reporting measures as of 2014

Contact Information

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References

1. CAP 15189 website www.cap.org/cap15189
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3. Bates, D. W., Goldman, L., Lee, T., Contaminant blood cultures and resource utilization. The true consequences of false-positive results. *JAMA: The Journal of the American Medical Association*, 1991; 265: 365-369.