



Certification Workshop:
Data Analytics for Lean and Six Sigma
Practitioners: Using Data to Make Smarter
Decisions while Selling Your Projects to
Administration

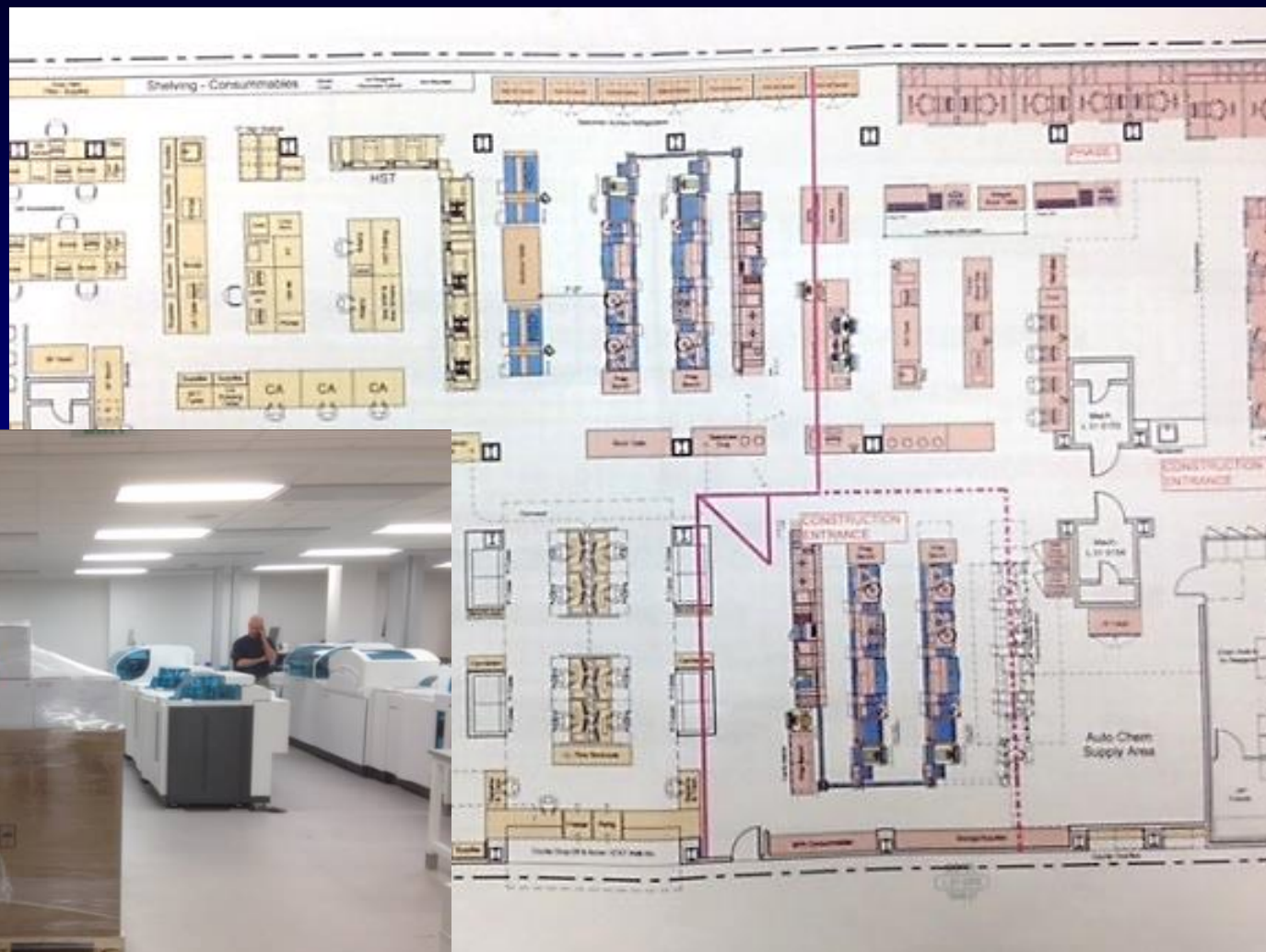
Lab Quality Confab
Ed Reineks, MD/PhD
October 2016

Objectives

- Describe the history of my pursuit of data and analytics resources in a large, complex lab and health system.
- Describe several scenarios where data gathering and organization serve to influence and drive decisions by lab admin executives and/or medical leadership
- Show the variety of applications
- Highlight limitations of analysis: e.g. systemic or transient barriers, scope of perspective, regulatory, etc.

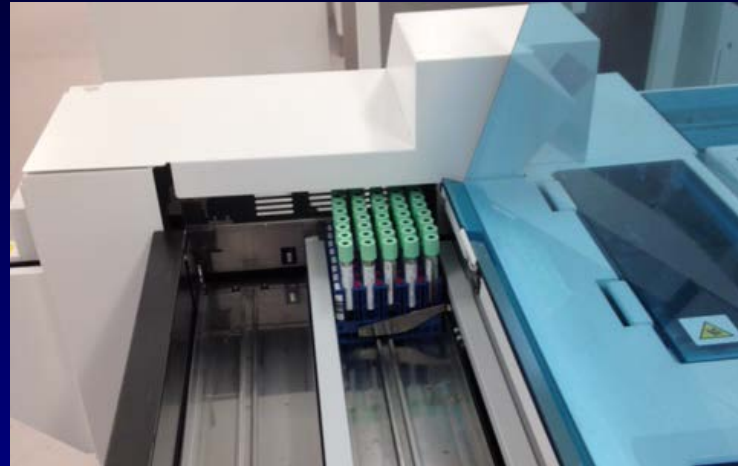
Characteristics

- Automated chemistry lab
 - Cobas8000 lines (Roche) x4
 - Other stand-alone instruments
 - ~7000 samples/day; 16 million results/year
 - STATs from ED, Cancer center, ORs, dialysis
 - Also serves as “24/7/365” chemistry
- Blood gas lab (ORs, ICUs)
 - >3 million annual results
- Point of care program
 - Waived and non-waived programs
 - >100 CLIAS, ~1000 instruments, >10000 operators



Automated Chemistry and Blood Gas Lab

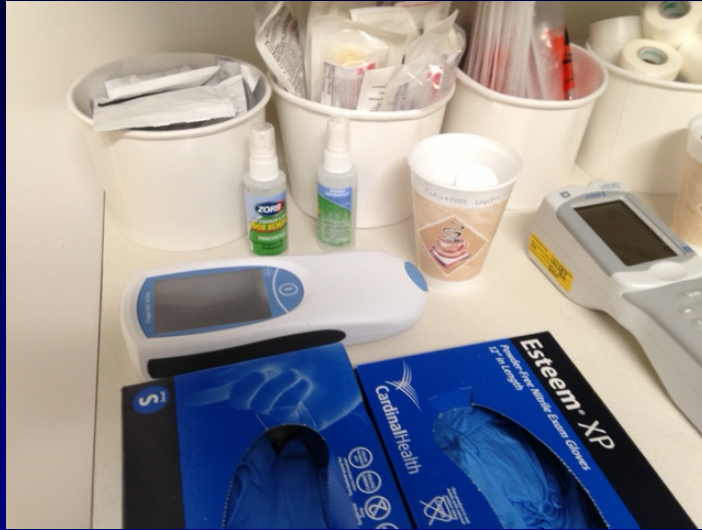
- Highest volume laboratories in Cleveland Clinic, and possibly highest volume hospital laboratory in US. (24/7/365)
 - Autochem: ~7000 tubes/day
 - 16 million test results per year
 - Blood gas lab: ~800 to 1000 samples/day



Core Lab At Work

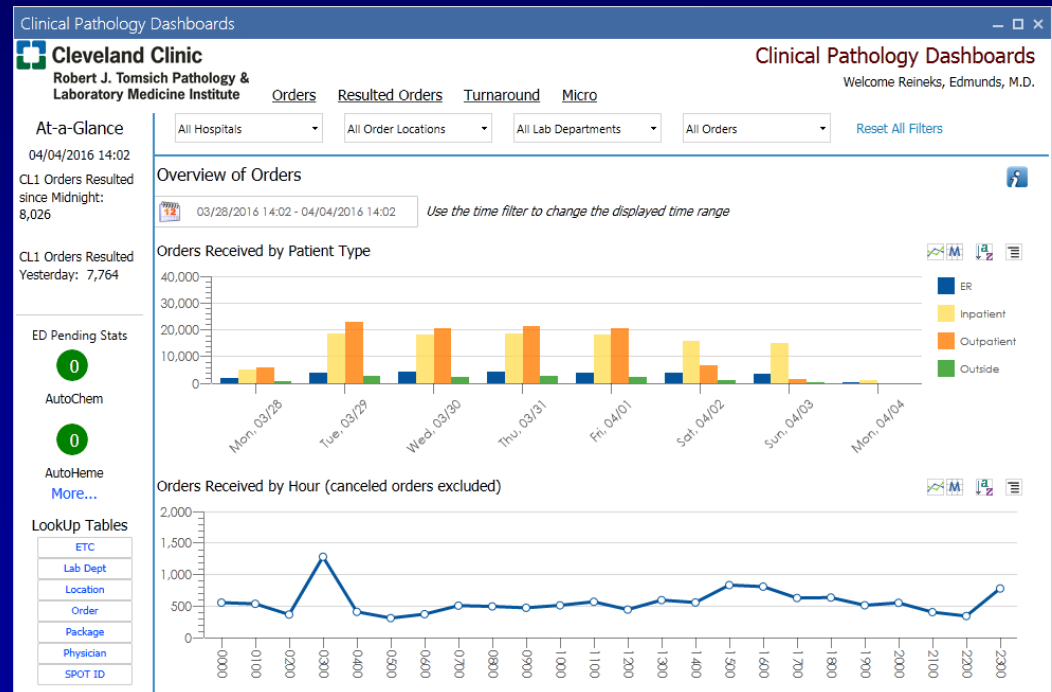


Point of Care Testing: Ebola lab, Mobile Stroke

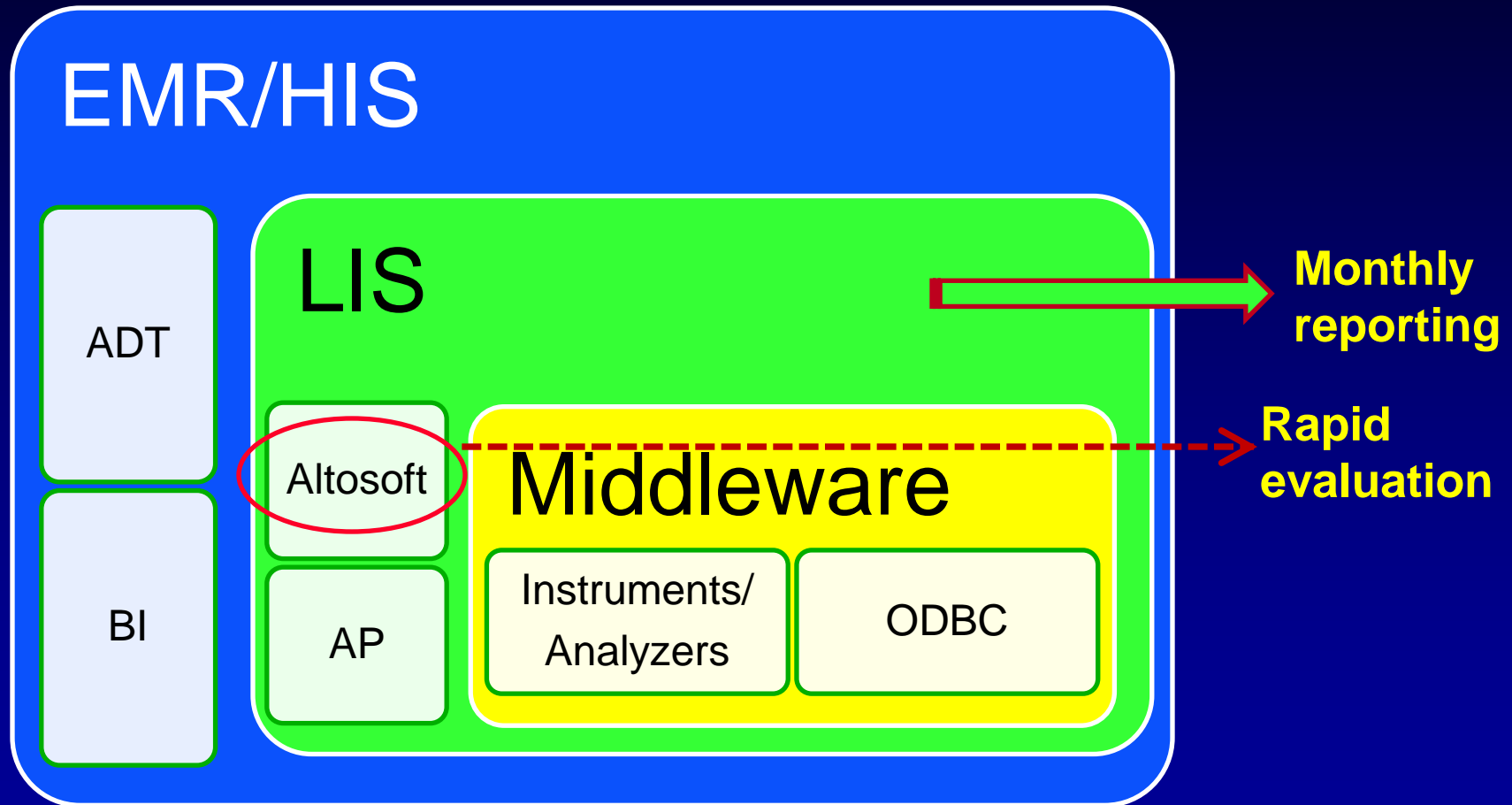


Laboratory Informatics

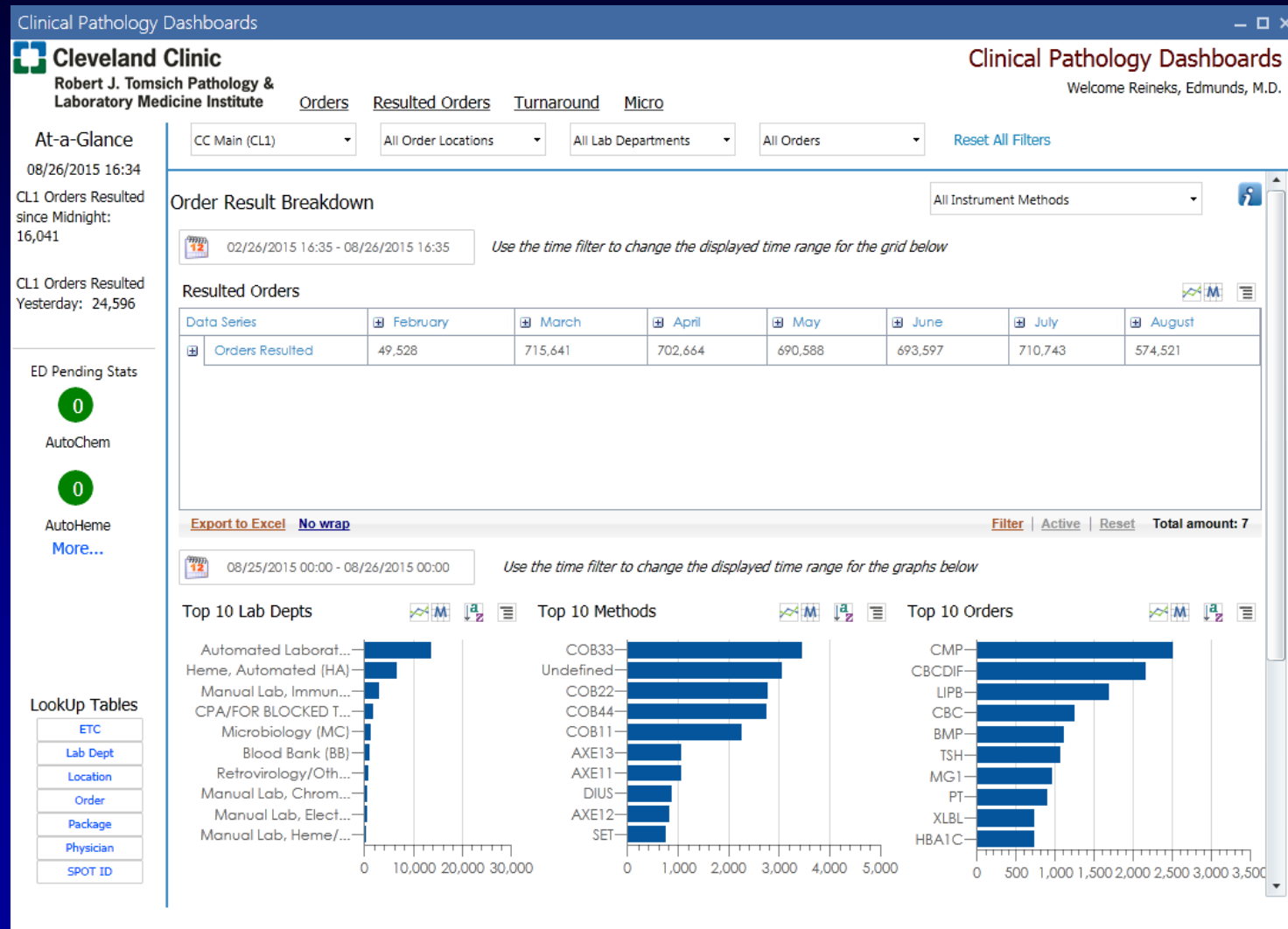
- LIS for lab is Sunquest(SQ)
 - Ad lib searching not user-friendly
 - Automated reporting possible
- Altosoft BI (Kofax, Lexmark)
 - Extracts SQ data
 - Reorganizes
 - Searchable
 - Exportable
 - Dashboards
 - No coding



Laboratory Informatics

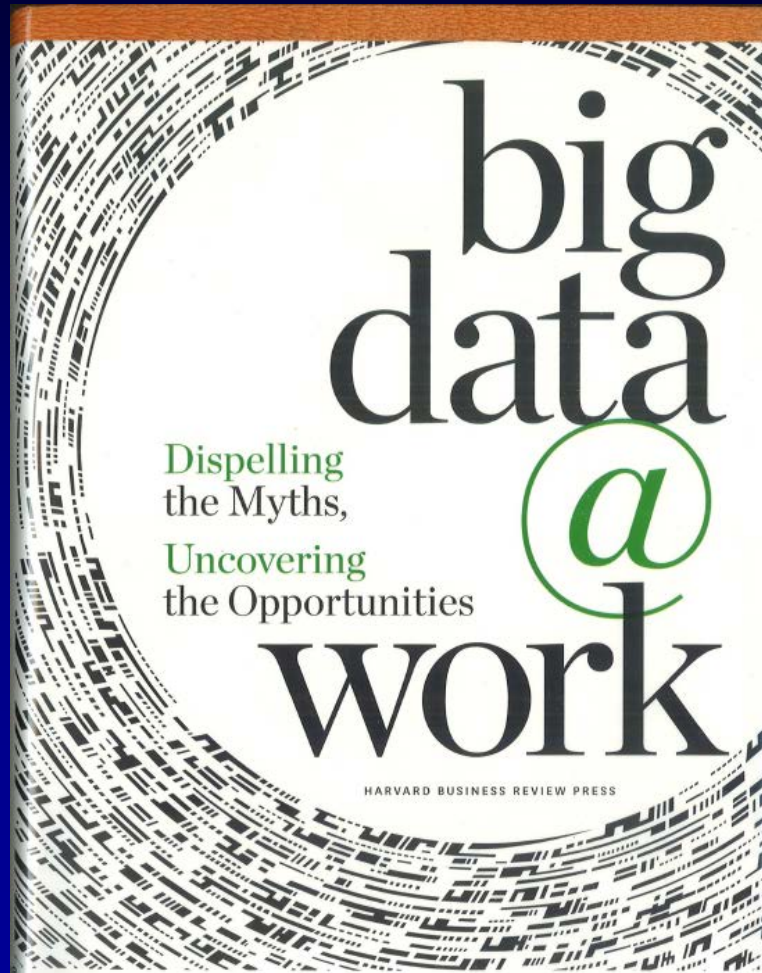


Current State: Altosoft shows Autochem is Busiest Lab Area



Traits of Data Scientists

per Thomas Davenport



Hacker

- Ability to code
- Understanding of big data technology architectures

Scientist

- Evidence-based decision making
- Improvisation
- Impatience and action orientation

Trusted adviser

- Strong communication and relationship skills
- Ability to frame decisions and understand decision processes

Quantitative analyst


- Statistical analysis
- Visual analytics
- Machine learning
- Analysis of unstructured data, such as text, video, or images

Business expert


- Know how the business works and makes money
- Good sense of where to apply analytics and big data

Before any Business Intelligence Software: Customized Status Board

File Edit View Favorites Tools Help



>>

**Cleveland Clinic**
Pathology and Laboratory Medicine

Test Code:

TROPT	CRET
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Grace Period / Max Display Time:

25/300	25/300
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Current Date/Time: 10/05/2016 15:19

StatTAT Mon. (Auto Chem.)

Last Sunquest Update: 10/05/2016 15:18

Warning	Overdue	Preliminary
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Acc. No.	Bat/Test Code	Lab Dept	Received D/T	Minutes Since Received	Pt. Name	Pt. Number	Pt. Order Loc	Ordering Phy. Name
W2027292	TNT / TROPT	CCOR	10/05/2016 14:34	45			E12	QUEEN,JOHN
W2026895	TNT / TROPT	CCOR	10/05/2016 14:41	38			E12	CASTILANO,
W2027054	CMP / CRET	CCOR	10/05/2016 14:23	56			E12	RATHZ,DEBO

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Core Lab At Work –Status Boards



Application of Serum Indices

- **Background:** A community hospital in our health system was facing intense regulatory scrutiny following a CMS inspection (validation survey)
- A significant amount of testing was being re-validated under scrutiny of lab leadership, outside consultants, and government regulators.
- Package inserts (IFUs) for waived and moderate complexity tests *must* be followed, and contain language such as “no interference is detected at a hemoglobin concentration of XXX.”
- Your system allows measurement of hemolysis index (dimensionless), which may be roughly converted to hemoglobin concentration. What do you have to do to observe package insert instructions?

Application of Serum Indices

- Is interpretation absolute or a spectrum?
 - Inspectors are more specific than CLIA or the interpretive guidelines.
 - We were told the lab was deviating from the IFU unless they assess for hemolysis and cancel if hemolyzed. (None of that is stated in the IFU.)
- What is the impact on patient care?
- What are the alternatives, if any?
- Will health system leadership apply this standard across the enterprise?

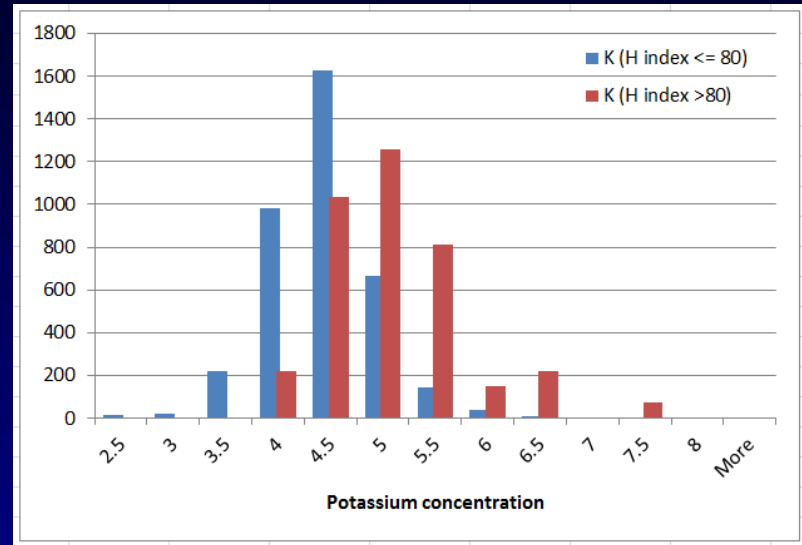
Application of Serum Indices

- **Patient care impact**
 - **This is why it came to my attention: main campus started to receive many specimens for analytes that were available at the community hospital; from ED patients!**
 - **When we investigated, we learned the original STAT tests were cancelled due to hemolysis, and re-draws were ordered routine, and sent to main campus since we didn't cancel them.**

Application of Serum Indices

- Requirements vs. interpretation
- Is it just good practice?
- Risk assessment
- Arbitrary interpretation (biotin, rheumatoid factor, anti-ruthenium antibodies)
- Competing interests: quality/compliance, resource use, impact on performance, commitment to patient care

Application of Serum Indices



Application of Serum Indices

- Take aways:
 - Avoid regulatory scrutiny to the extent possible
 - Know the impact of decisions on operations: provide data if possible
 - Patient care
 - Resources
 - Compliance

Pre and post analytic audits in Point of Care Testing

- **Self assessment of compliance and quality gaps; incorporated in SLAs**
 - **Manual data gathering; labor intensive, but increased level of engagement**
 - **Results influenced hospital leadership: middleware, device connectivity, compliance tracking**
 - **Increased efficiency**

Pre-Analytic and Post-Analytic Monitoring Forms

- Forms are completed by Point of Care Testing locations
- Completed forms are submitted monthly to Lab
 - Forms are reviewed by Lab
 - Completion is tracked by Lab
- Pre-Analytic Forms cover:
 - Package Inserts
 - Temperature and Humidity Monitoring
 - Reagent Expiration Dates
 - Testing Personnel Updates
- Post-Analytic Forms cover:
 - Review of Patient Results

Temperature and Humidity Monitoring

Month / Year of Audit: _____

Instruments / Temperature Requirements:

"Please review package inserts to ensure no temperature and humidity ranges have changed. Has package insert been checked? Please circle: Yes No"

- i-Stat Temperature
 - Instrument – 16°C – 30°C
 - Cartridges – 2°C – 8°C Refrigerated
 - Kaolin ACT - 18°C – 30°C Room temperature. Expires in 14 Days.
 - QC – 2°C - 8°C
 - 18°C – 30°C Room temperature. Expires in 4 hours.
- i-Stat Humidity
 - Instrument – 0 – 90%
 - Cartridges – N/A
 - QC – N/A

Audit

- Ambient Temperature:
 - Was ambient temperature in range, yes or no, if no was appropriate corrective action taken, please explain?
 - Prep and Recovery Yes No
- Ambient Humidity:
 - Was ambient humidity in range, yes or no, if no was appropriate corrective action taken, please explain?
 - Prep and Recovery Yes No
- Was the Temperature/Humidity monthly log reviewed and signed off on?
 - Prep and Recovery Yes No
- Refrigerator Temperature:
 - Was refrigerator temperature in range, if no was appropriate corrective action taken? (Please list specific dates / examples)
 - POC Refrigerator Yes No

Audit Tracking Tool

- Monitored monthly by Lab
- Tracks all pieces of monthly audit, including:
 - Submission of Pre and Post Analytic Forms
 - QC Audit completion by Lab
 - Temperature Log audit completion by Lab
 - Correlation completion
 - Calibration Verification completion
 - Proficiency Test review
- Presented to POC Compliance Council monthly
 - Members include:
 - POC Medical Director
 - POC Manager
 - POC Specialists
 - Quality Institute
 - POC Location Contacts
 - Emergency Department Physicians
- Key
 - 1-Missing or late QC
 - 2-QC not rotated
 - 3-QC failures not addressed

Main Campus	POC Specialist: Desiree Dunnett, Jacob Higbie							
CLIA Holder: Dr. Reineks								
	January	February	March	April	May	June	July	August
Monthly								
Pre and Post Analytic Audit								
Adult Cath Lab								
AMET								
CMET								
Emergency Department								
EP Lab								
Interventional Radiology								
NICU M31 Respiratory								
PICU M43 Respiratory								
PICU M53 Respiratory								
PICU (M43) Nursing								
Pediatric Cath Lab								
Pediatric Perfusion								
Perfusion Services								
Prep and Recovery								
Pulmonary Function								
Radiology								
Syncope								
Vascular Surgery								
Quality Control Audit								
Adult Cath Lab				1	1	1, 3	3	ACT only
AMET								
CMET								
Emergency Department								
EP Lab								
Interventional Radiology								
NICU/PICU								
PICU (M43) Nursing				1				
Pediatric Cath Lab					1, 3			ACT only
Pediatric Perfusion		1		ACTOC paperwork		3		
Perfusion Services	1	1	1	1	1	1		ACT only
Prep and Recovery		3		1	1	1		
Pulmonary Function								
Radiology								
Syncope								
Vascular Surgery	1, 2	1, 2, 3	1, 2, 3		3	3		
Temperature Audit								
Adult Cath Lab								
AMET						1		
CMET								

Lessons Learned from Pre/Post Audits

- **Time change not completed on an ACT device that wasn't interfaced during Post-Analytic audit.**
- **Avox results were being rounded, instead of reported exactly as presented on the instrument. Detected during Post-Analytic audit.**
- **An OR was having sustained temperature issues that was detected during Pre-Analytic audits of temperature logs.**
- **Temperature ranges listed on some OR temperature logs were incorrect. This was caught when the POC location compared the log to the Pre-Analytic form.**
- **Locations are cycling through reagents according to soonest expiration dates. Noticed while performing Pre-Analytic audit.**
- **Locations have discovered and discarded expired reagents during the Pre-Analytic audit.**

Challenging Externally Applied Productivity Metrics

- **Requires deeper understanding of metric source and applicability**
 - **Additional data from other lab areas for comparison**
 - **Also investigated published productivity data**
 - **Highlighted inappropriate application and conclusions to request FTE add.**

Staffing Benchmarks for Clinical Laboratories

A College of American Pathologists Q-Probes Study of Laboratory Staffing at 98 Institutions

Table 4. Distribution of Staffing Ratios^a

Table 4. Distribution of Staffing Ratios ^a				
Ratio	No.	All Institution Percentiles		
		10th	50th (Median)	90th
Anatomic pathology section				
Tissue blocks per histology nonmanagement FTE				
2004	116	3922	6908	12 125
2010	74	2845	7482	13 390
Cytology accessions per cytology nonmanagement FTE				
2004	101	1545	4067	9253
2010	61	1533	4072	8526
Nonmanagement FTEs per management FTE				
2004	114	3.0	7.6	19.5
2010	69	2.0	8.4	22.8
Chemistry/hematology/immunology section				
Total billable tests per nonmanagement FTE				
2004	149	17 979	42 674	90 183
2010	93	18 462	52 647	117 616
Nonmanagement FTEs per management FTE				
2004	146	4.9	11.6	24.8
2010	92	5.0	11.1	20.2

2. For counting tests in the chemistry/hematology/immunology section, chemistry profiles were unbundled, in conformance with current Medicare billing requirements. Thus, an electrolyte panel consisting of 5 analytes is to be counted as 5 tests. However, components of a hemogram (hemoglobin, white blood cell count, platelet count, etc) were not unbundled, because this test has 1 CPT code and Medicare requires that it be billed only once for each hemogram. The

Summary: proper staffing for autochem/gas lab based on Q probes data and testing volume, accounting for CPA contribution to the effort, and based on the 90th percentile of productivity, shows we should have about 128 bench FTEs and 2 *additional* management FTEs. Currently we have 48 authorized. Details:

- Autochem test volume based on core lab and blood gas lab
 - Core lab \approx 16 million per year
 - Gas lab \approx 3 million per year
- 90th percentile productivity is about 120,000 annual tests/tech
- Central processing techs are also considered in Q probes analysis
 - About 1/3 of PLMI specimens are routed to autochem
 - FTE staffing in CPA is about 60; so 1/3 (to attribute to autochem workload is 20)
- $19,000,000/120,000 = 158$ FTEs
- Subtract the CPA fraction: $158 - 20 = 138$ FTEs
- CPA is likely understaffed, so let's put them at 30. Then, $158 - 30 = 128$ FTEs
- Q probes also has management (non-doctoral level) staffing as 1 management FTE/20 bench techs. So autochem should have about 6 FTEs who manage and don't work the bench; currently, we have 2 (in autochem), plus 1/3 manager and a fraction of 2 administrators (if we count Jane, Rob, and Lisa: $3 * 1/3 = 1$)
- So we should have three more management FTEs
- For perspective, based on median (50th percentile productivity), we would staff at a level of 280 bench techs.

Staffing model #2, using Management Engineering Data and adjusting for the manual testing performed by autochem

Summary: proper staffing for autochem/gas lab based on management engineering data and testing volume shows we should have about 54 bench FTEs. Currently we have 48 authorized. Details:

Autochem has two cost centers: the core lab and blood gas lab. We have gathered data to show that 12% of core lab autochem specimens are truly manual, rather than automated, in their handling (either a manually performed test, or a test requiring manual resulting, a rerun, dilution, pre-analytic processing, etc.). Reclassification of 12% of our volume from the autochem HPU of 0.021 to the immunopath HPU (which is most comparable) of 0.054, would result in an **additional 6 FTEs**.

Staffing model #3; based on current use of overtime and temps

Overtime Hours	Jan-16	Feb-16	Mar-16
Night Shift	62	48	113
Day Shift	102	147	82
Evening Shift	66	53	50
Total	230	248	244
Temp Hours	Jan-16	Feb-16	Mar-16
Night Shift	184	168	184
Day Shift	288	336	196
Evening Shift	168	168	160
Total	640	672	540
OT + Temp Hours	Jan-16	Feb-16	Mar-16
Night Shift	246	216	297
Day Shift	390	483	278
Evening Shift	234	221	210
Total	870	920	784
40 Hours (4 weeks) = 1 FTE	Jan-16	Feb-16	Mar-16
Hours	870	920	784
FTEs needed	5.4	5.8	4.9

Silos in Financial Performance Evaluation

- **Overall cost and performance goals secondary to silo needs**
- **Cost shifting examples**
 - **Process**
 - **Barriers**
 - **Examples from Lab and POC**

Things We Did Well

Things We Could Have Done Better

Thanks and Acknowledgements



Cleveland Clinic

Every life deserves world class care.