



MedStar Georgetown
University Hospital

Knowledge and Compassion
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May 2, 2012

Lessons Learned in Anatomic Pathology Lab Accreditation and Licensure: What Inspectors Often Miss and How We Responded to a Crisis

Executive War College 2012

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Objectives

- How we handled the CMS & CAP Unannounced Inspection
- How we responded to the crisis
- Lessons learned
- Could this have been prevented?
- Laboratory structure today
- How to move beyond the crisis

Laboratory Structure at MedStar Georgetown University Hospital (MGUH)

- Georgetown University sold Georgetown University Hospital to MedStar Health in 2000
- MedStar Health is a 9 hospital health system in Baltimore, MD / Washington, DC area
 - All of the laboratories are interconnected and function as one unit
 - One LIS; Share Samples between labs; Conduct internal inspections; Multi-disciplinary workgroups; Same equipment; etc
- Until 2010, Pathology & Laboratory Medicine at MGUH functioned as two separate departments
 - Different Laboratory Directors
 - Different Administrative Directors
 - Separate CLIA & CAP numbers
 - Separate locations
- Before 2002, MGUH Pathology was accredited by JCAHO. Starting in 2003 both MGUH Pathology & Laboratory Medicine were accredited by CAP.

Laboratory Structure at MedStar Georgetown University Hospital (MGUH)

- Laboratory Medicine Sections
 - Core Lab (Chemistry, Hematology & Coagulation)
 - Blood Bank
 - Microbiology
 - Histocompatibility (HLA)
 - Cellular Engineering
 - Specimen Collection & Central Processing
- Pathology Sections
 - Surgical Pathology, Histology & Autopsy / Morgue
 - Cytology
 - Electron Microscopy & Immunofluorescence
 - Molecular Diagnostics (IHC, FISH, Flow Cytometry & PCR)

Laboratory Structure at MedStar Georgetown University Hospital (MGUH)

- Molecular Diagnostics Test Menu (*July 2010*)
 - IHC
 - Over 250 different antibodies
 - FISH
 - 3 Analytes
 - Her2, EBER, 1p/19q, d(1;19)
 - Flow Cytometry
 - 15 customized panels
 - PCR
 - 24 Analytes
 - VDJ; Ty; EBNA; t(9;22); HPV; JAK2; t(15;17); BCL-2; BCL-1; KRAS; BRAF; INV16; t(8;21); HHV8; TBC; t(12;21); t(1;19); t(11;22); HHV6; HHV7; t(2;13); t(X;18); t(2;5); t(6;9)

CMS & CAP Unannounced Inspection – July 2010

- CMS & CAP appear at MGUH to conduct a joint unannounced inspection in response to a complaint about Her2 testing
 - CAP completes a 2-day inspection of the Pathology sections focusing on the Anatomic Pathology, Flow Cytometry & Laboratory General Checklist
 - Responses to CAP citations due in 10-calendar days
 - CMS stays at MGUH for an additional 7-days focusing on the Molecular Diagnostics Section (IHC, FISH, Flow Cytometry & PCR)
 - Final report to follow
 - After CMS leaves, 2nd CAP arrives the next day to conduct another inspection focusing on the Molecular Diagnostic & Cytology Checklist
 - Responses to CAP citations due in 10-calendar days

Unannounced Inspection Findings

- **No concern** with reliability & accuracy of the patient test results conducted within the department
- Documentation Needs:
 - Quality Management Program representing all laboratory sections
 - Validation Studies
 - Easy to follow policy & procedure manuals
 - Staff competency assessments
 - Reviews of instrument logs, reagent logs & quality control
 - Proficiency testing follow-up
- Poor Inspection Preparedness
- **Key tag line**: If it is not documented, it was not done.

Key Areas Needed to be Addressed

- Most areas of the Molecular section offered very customized & pathologist driven protocols
 - Homebrew PCR tests & Flow panels
 - Over 250 IHC antibodies; many with low volume
 - No standardization among all of the faculty members
- Less experienced technical staff
- Limited staff within the molecular section
- Lack of defined technical leadership who understood how to apply the laboratory regulations
- Misconception of laboratory regulations among the staff & the faculty members

What to do next?

- Suspended technical testing within the Molecular laboratory
- Formed a team to focus on responding to the CAP citations
- Another team was formed to focus on responding to the CMS report
- A central repository of all inspection reports, findings and responses created in hospital performance improvement & regulatory affairs
- Hired an Interim Quality Management Coordinator
- Established a project plan
- MedStar Corporate & MGUH Leadership assistance

Key Next Steps

- Re-designed each procedure manual
 - Procedure manual set-up by testing assay
 - Each manual has a procedure on quality control, validation, technical testing process, instrument care, etc
- Adopted a proficiency testing checklist form from the clinical laboratory to ensure all requirements are adequately documented
- Assigned staff to key deliverables (QC review, procedure writing, etc)
- Evaluated test menu & established a partnership with a reference laboratory for the low volume tests
- Re-validated each assay or antibody within the Molecular laboratory (***100% of all Molecular Tests***)
 - Key pathologists were assigned to specific areas
 - Positive & negative controls reviewed and assigned as part of the re-validation efforts

Key Next Steps

- Applied standardization within the Molecular Laboratory
 - A statement about positive & negative controls added to the pathology report which is dictated by the pathologist
 - Standard form & process established and used to validate current & new assays
 - Form outlines all six of the CLIA performance characteristics
 - Validation summary meeting with Laboratory Director
 - All of the key inspection deficiencies were added to the Quality Management Program meeting as key performance characteristics (QC log review, test validation, staff training, proficiency testing status, etc.)
 - Homebrew assays were removed from the test menu
 - All new testing was discussed with the Laboratory Director and then reviewed at the faculty meeting
 - Schedule drafted and process adopted for supervisory review of QC, reagent logs, etc.

Key Next Steps

- Faculty & Staff Re-education & Participation
 - Culture change was implemented
 - Each person was assigned a key task and/or process; not a supervisor led or laboratory director led change
 - Open forum
 - New policies and procedures were discussed with all faculty & all staff present
 - Once the new policy or procedure was established, everyone signed to document their acceptance & understanding
- Personnel Structure Re-design
 - Laboratory Director title & responsibilities delegated from Chairman to another pathologist (*matching CP structure*)
 - Laboratory Supervisor was hired to oversee technical operations of the Molecular section
 - Quality Management Coordinator hired to cover both Pathology & Laboratory Medicine

Laboratory Structure at MedStar Georgetown University Hospital (MGUH)

- Molecular Diagnostics Test Menu

Lab Section	January 2011	July 2010
IHC	147 antibodies	Over 250 Antibodies
FISH	<ul style="list-style-type: none"> • 2 Analytes Her2; EBER 	<ul style="list-style-type: none"> • 3 Analytes Her2; EBER; 1p/19q, d(1;19)
Flow Cytometry	8 standard panels	15 customized panels
PCR	<ul style="list-style-type: none"> • 11 Analytes VDJ ; IGH (InvivoScribe Kit); T-gamma; t(15;17); JAK-2 (Qualitative); JAK-2 (Real-Time); BCL-1; BCL-2 (InvivoScribe Kit) ; HPV (16 & 18); BCR-ABL (Qualitative); BCR-ABL (Quantitative) 	<ul style="list-style-type: none"> • 24 Analytes VDJ; Ty; EBNA; t(9;22); HPV; JAK2; t(15;17); BCL-2; BCL-1; KRAS; BRAF; INV16; t(8;21); HHV8; TBC; t(12;21); t(1;19); t(11;22); HHV6; HHV7; t(2;13); t(X;18); t(2;5); t(6;9)

Summary Timeline

- July 2010
 - CMS & CAP on-site inspections
- August 2010
 - CAP citation responses due / submitted & accepted
 - CMS final report issued & responses due / submitted & accepted
 - Technical Testing Suspended in Molecular Laboratory
 - Final documented reports from CAP & CMS complimentary submitted to JC
- September, October, November 2010
 - Monthly progress updated submitted to CAP, CMS & JC
 - Pathology Laboratory Direction change
 - New Laboratory Supervisor for Molecular Diagnostics
- December 2010
 - CMS re-validation 5-day inspection
 - Technical Testing resumed in Molecular Laboratory
 - New Quality Management Coordinator for Pathology & Laboratory Medicine
- January 2011
 - CAP re-validation 1-day inspection
- August 2011
 - Regular CAP inspection with JC inspectors present

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Lessons Learned

- Anatomic Pathology is **not exempt** from the CLIA regulations or the Laboratory General CAP Checklist
- Constant & frequent communication with the regulatory agencies (CAP, CMS & JC)
- Open and honest communication with hospital administration
- Use this an opportunity to ask for advice & assistance from peers as well as from the regulatory agencies
- Faculty & staff participation, buy-in and open communication is essential
- Both clinical pathology & anatomic pathology must fulfill the same basis regulations; it is important to have a few key people to understand and know how to apply these concepts across both sides of the department(s).
- Overcoming this type of an obstacle requires strong physician leadership & administrative leadership to be partnered together. **TEAMWORK**

Could this have been prevented?

- **YES**
- These type of issues do not develop overnight
- Pay attention to:
 - Previous citations
 - Faculty & Staff's knowledge of the regulatory requirements; how they apply to their area of expertise; understanding of why certain things are important.
 - Proficiency Testing results
- Too much customization and lack of attention to detail can be an enemy
- Do not overlook a checklist question because it would require much effort to meet the intention of the guideline.
- Ensure that whomever conducts the internal inspection has an appreciation and accurate understanding of the checklist.

Did the previous inspectors miss something?

- **NO**
- Previous citations were issued
 - Lack of understanding of their importance
 - Lack of understanding on how to apply the standard
- CAP's new checklists
 - Checklists today list specific items of compliance in an easy to follow format
 - Refined training for inspectors with CAP is much more robust
- In the end, it is the responsibility of each laboratory to utilize the resources available to comply with the regulations
 - Continuing education conferences
 - Inspection manuals
 - Outside publications
 - Outside consultant observation & review

Laboratory Structure at MedStar Georgetown University Hospital (MGUH)

- Molecular Diagnostics Test Menu

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IHC	142 antibodies	147 antibodies
FISH	<ul style="list-style-type: none"> • 2 Analytes Her2; EBER 	<ul style="list-style-type: none"> • 2 Analytes Her2; EBER
Flow Cytometry	8 standard panels	8 standard panels
PCR	<ul style="list-style-type: none"> • 17 Analytes VDJ ; IGH (InvivoScribe Kit); T-gamma; t(15;17); JAK-2 (Qualitative); JAK-2 (Real-Time); BCL-1; BCL-2 (InvivoScribe Kit) ; HPV (16 & 18); BCR-ABL (Qualitative); BCR-ABL (Quantitative); HIV; HCV; HBV; Factor II; Factor V; MTHFR 	<ul style="list-style-type: none"> • 11 Analytes VDJ ; IGH (InvivoScribe Kit); T-gamma; t(15;17); JAK-2 (Qualitative); JAK-2 (Real-Time); BCL-1; BCL-2 (InvivoScribe Kit) ; HPV (16 & 18); BCR-ABL (Qualitative); BCR-ABL (Quantitative)

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Laboratory Today at MedStar Georgetown University Hospital (MGUH)

- Within the health system, MGUH has evolved into the site with the molecular diagnostic, coagulation and HLA specialty.
- Much higher appreciation and understanding of the laboratory regulations.
- Regulatory Requirements & Inspections is hardwired into the staff and a large part of new employee orientation
- Focus is now on LEAN, further integration of Pathology & Laboratory Medicine and growing the molecular diagnostics testing section
- Separation can still work
 - Still have separate CLIA & CAP numbers, separate Laboratory Directors, separate locations;
 - One Chairman, one Administrative Director, one Quality Management Coordinator and a much more refined department

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Questions?

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