Doctor of Clinical Laboratory Science (DCLS) Contributing Quality and Value in Clinical Laboratory Services Delivery

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Learning Objectives

• Assess the evidence of the need to improve the delivery of clinical laboratory diagnostic services.

• Define the Doctorate in Clinical Laboratory Science.

• Describe the Diagnostics Consultation Model (DCM©).

• Evaluate the contribution of DCLS consultations related to patient safety, quality patient care, and cost.
Laboratory Services - Central to Patient Diagnosis

- Physician Offices
- In-Patient Care
- Home Care
- Post Hospital
Need for Improvement in Delivery of Laboratory Services

Expanding Lab Test Menu

Medical Errors

Laboratory Services

Challenges: Ordering & Interpreting Test Results

High Costs of Health Care
2007: CDC: Division of Laboratory Systems
Institute: Managing for Better Health. Executive Summary: Action Plan Priorities. Explore ways of improving the integration of lab medicine within the health system….

“to institutionalize new models of clinical consultation provided by the laboratory medicine professionals to clinicians to guide their decisions about utilization of laboratory tests or services”.

2013: Clinical Laboratory News January 2013, Vol. 39, No.1
A Family Physician's Perspective on Laboratory Testing and Diagnostic Errors Interview with Peter Weir, MD, MPH
• Potential for ordering the wrong test…..over-order tests if uncomfortable with a clinical situation
• Ordering panels of lab tests, not well thought-out, leads to confusion, unnecessary referrals
• Bring clin lab expertise to our clinic
• Collaboration with colleague’s for better patient care
Quality Gap Between Clinicians and the Laboratory


- Challenges in ordering
- Interpreting diagnostic laboratory tests
- Safe and efficient use of laboratory testing resources
- Quick access to laboratory consultations

2015: Institute of Medicine Improving Diagnosis in Health Care

- Diagnostic errors cause patient harm
- Improvement in the diagnostic process requires collaboration among physicians and laboratory professionals.

2017: Opportunities to Enhance Laboratory Professionals’ Role On the Diagnostic Team. *Laboratory Medicine*. Vol 8. Issue1, Feb 2017

- 31,689 with 1768 (5.6%) response; Diagnostic challenges, use electronic resources
- Difficult and time-consuming to contact the lab
- "Laboratory professionals have an opportunity to play a greater role in the diagnostic process by becoming active members of the clinical care team, beyond providing results.”
2018: The Laboratorian as a Clinical Consultant: Identifying Needs and Building New Roles
Cardinal Health Webinar April 25, 2018

Need for laboratorians

- Expand their sphere of influence outside the walls of the clinical laboratory
- Opportunities in institutions for expanding the professional role of clinical laboratorians
- Key clinical and administrative partners for a successful program that fully utilizes the skill set of the laboratorian
THERE IS A COMMON THEME

Ordering the Correct Test (most often noted)

Interpreting Results

Laboratorians on Healthcare Teams

Optimal Utilization Laboratory Services/Resources
Interprofessional Health Care Teams

Physicians
Medical Residents

Clinical Laboratory Professional?

Healthcare Team

PharmD Nurses

Physician Assistant
DCN, PT
Medical Students
Addressing the Gap & Meeting the Need

2005: American Society for Clinical Laboratory Science (ASCLS)
Advanced Practice Doctorate in Clinical Laboratory Science Position Paper
(Reviewed/revised: 2013, 2016)

“Development of the medical laboratory scientist to assume a role as a member of the interprofessional healthcare team requires advanced knowledge and clinical training.”


DCLS Oversight Committee
- Development
- Implementation
- Integration
- Evaluation
DCLS - Advanced practice doctorate

- Certified medical laboratory scientists

Partner with clinical pathology to provide value of diagnostics through consultation throughout the healthcare sector

- Consult with clinicians and healthcare professionals regarding lab test ordering
- Evaluate/interpret lab test results, integrate data
- Consult to assure quality utilization of laboratory services
- Develop evidence-based guidelines and policy
- Utilize EMR and LIS analytics-supports quality programs

Conduct Outcomes Research

- Focus on the impact of diagnostics on clinical/health outcomes.
PhD vs Professional Practice Doctorate
What’s the Difference?

PhD, ED.D, D.Sc., etc.
• Curriculum emphasis is on research and scholarship (>50% of overall credits)
• Candidacy exam/dissertation

Entry-Level Practice Doctoral Degree (MD, PharmD, DPT, D.C. DM.D, J.D.)
– Focus is on clinical practice
– Degree related to becoming licensed and/or 1st credential to practice
– Clinical component in the curriculum (not included in PhD)
– Applies research, usually does not include a research project

Advanced Practice Doctoral Degrees (DCLS, DNP, DCN)
• Focus is on advanced clinical practice, requires clinical expertise
• Prepares for highest level of practice beyond the initial preparation in the discipline.
• Requires certification/credential and/or licensure in the profession prior to beginning the program
• Clinical component in the curriculum (not included in PhD)
• Includes an independent research project; < 30% of overall credits related to research

Middle States Commission on High Education Degrees and Credits,2006.
Rutgers University-DCLS

- 1st advanced practice doctorate for certified MLS in the US
- 1st graduate, May 2018; employed as a DCLS

Curriculum: 80 credits beyond the BS degree

- Certified medical laboratory scientist (MLS)
- Blended: Web-based for theoretical courses + practice/residency
- FT & PT options for pre-residency component (theoretical courses)
  - Advanced Clinical Laboratory Science Core – 30 credits
  - Professional Core – 15 credits
  - Research Core – 21 credits
  - Clinical Practice/Residency – 14 credits

- FT One Year Clinical Practice/Residency
Provide patient-centered care

Work in interdisciplinary teams

Employ evidence-based practice

Apply quality improvement

Utilize informatics

From: Institute of Medicine
Health Professions Education: A Bridge to Quality, 2003.
Framework for DCLS to address the quality gap in clinical laboratory services delivery

Patient Care Intervention (PCI)
- Daily patient-care clinical rounds - Interprofessional healthcare team

Diagnostics Management Intervention (DMI)
- Encounters received via direct case management requests to the clinical laboratory

Utilization Review Intervention (URI)
- Encounters through review of reports generated by the LIS system/rules

Community Intervention (CI)
- Consumer information response encounters
  - Lab Test Online (labtestsonline.org)
    - Questions answered by a medical laboratory scientist as part of a voluntary service provided by American Society for Clinical Laboratory Science (ASCLS).
  - Other community-based setting
Data Collection & Analysis

Practice & Research

Practice

Daily Activities of Value

Prioritize schedule based on need

Research

Develop laboratory:
• Quality plans
• Algorithms, Protocols, Guidelines

Identify clinical laboratory topics for inter-professional development

Provide evidence & best practices
Case Examples

• Encounters during DCLS residency
• How the DCLS interacts with the healthcare team
• Demonstrates the contribution of DCLS

*Brandy Gunsolus, DCLS, MLS(ASCP)CM, documented during her DCLS residency as part of the requirements for completion of the Rutgers University DCLS degree.*
Case #1 – Patient Care Intervention (PCI)
Daily patient-care clinical rounds - Interprofessional healthcare team

Patient:
- 34-year-old male, quadriplegic
- Tracheal ventilator dependent
- Admitted from the ER to the Cardiology service for atrial fibrillation

Inpatient Day 2
- Cardiology care team determines patient needs a pacemaker
- Procedure scheduled for AM of Day 4

Overnight of Day 2
- Resident notified
  - MSSE growth in tracheal aspirate culture obtained in ER
  - Resident prescribed 10-day course IV vancomycin
- Documents patient as having MSSE pneumonia
Case #1

Patient Care Team – Inpatient Day 3
- Attending Physician
- Cardiology Fellow
- Resident Physicians
- Clinical Pharmacist
- DCLS Resident
- RN
- Care Coordinator

Pacemaker procedure must be postponed until IV antibiotic therapy is complete
- Requires 10 additional inpatient days

Attending physician asked the DCLS resident for opinion on culture result
Case #1

DCLS Consult:
• Patient has a permanent trach
• Grows a bacterial biofilm overtime
• MSSE is likely representative of this biofilm
• No growth on the Bronchoalveolar lavage (BAL) culture
• Chest x-rays - clear lung fields
• Vital signs do not indicate infection
• No evidence the patient has bacterial pneumonia
Case #1

Team Conclusion:
- Patient does not have bacterial pneumonia
- Cancel antibiotic regimen
- Move forward with pace-maker placement as originally scheduled

DCLS Consultation Contributed To:
- Correct patient diagnosis
- Discontinuation of inappropriate antibiotic therapy
- Decreasing patient length of stay by 10 days
- Patient obtaining pacemaker placement in a timely manner
- Cost savings of $22,300
Case #2- Patient Care Intervention (PCI)

**Patient:** 54-year-old male

- **PMH:**
  - Hypertension (HTN)
  - Aortic valve stenosis
  - Gastroesophageal reflux disease (GERD)

**Inpatient Day 4 in Cardio-Thoracic ICU**

- Post aortic valve replacement
- Extubated 20 hours earlier
- Now on full diet after 5 days NPO
Case #2

Day 3

Lab Results

- CBC - within reference range
- CMP - within reference range, except:

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine</td>
<td>1.49 mg/dL ↑</td>
</tr>
<tr>
<td>AST</td>
<td>54 U/L ↑</td>
</tr>
<tr>
<td>ALT</td>
<td>62 U/L ↑</td>
</tr>
</tbody>
</table>

- Acute Hepatitis Panel:
  - Non-reactive except HCV Ab +
Case #2

Patient Care Team:
- Attending Physician (CT Surgeon)
- Anesthesiology Fellow
- Resident Physicians
- Medical Students
- Clinical Pharmacist
- DCLS Resident
- RN
- Pharmacy Student

Day 4 Lab Results
- CBC – within reference range
- BMP ordered, only Potassium resulted
  - Potassium 6.2 mmol/L ↑ (hyperkalemia)
Case #2

Team Consult
During patient care rounds and team discussion

– Another patient in the unit coded
– Attending, fellow, and several residents left to take coded patient to surgery

A patient care plan had not been determined for the patient

• 2nd yr. resident physician assigned to the patient remained on the unit
• Requested the DCLS resident to assist in patient care planning
Case #2

DCLS Consult:
• Investigated why there were missing BMP results
• Assisted resident in locating previous test results
  – Patient was a known HCV+
  – Information not included on patient admission history & physical
  – Cancel HCV viral load
• Discussed a rhabdomyolysis case that occurred when full diet was initiated after extended NPO status
  – Rhabdomyolysis causes acute kidney injury and hyperkalemia

Suggested the following:
• Order BMP with new specimen collection
• Order Creatine kinase (CK) to assess for rhabdomyolysis
• Consult with Clinical Pharmacist
  – Therapeutic strategies to reduce potassium level
Case #2

Patient lab test results following consultation:

<table>
<thead>
<tr>
<th>Test</th>
<th>Current Result</th>
<th>Previous Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine</td>
<td>1.79 mg/dL ↑</td>
<td>1.49 mg/dL ↑</td>
</tr>
<tr>
<td>Potassium</td>
<td>6.4 mmol/L ↑</td>
<td>6.2 mmol/L ↑</td>
</tr>
<tr>
<td>CK</td>
<td>6,850 U/L ↑</td>
<td><em>Not tested</em></td>
</tr>
</tbody>
</table>

- Laboratory studies strongly suggestive of rhabdomyolysis
- Patient now complaining of muscle pain
Case #2

DCLS consultation contributed to the following outcomes:

• Provided previous lab tests results, cancelled unnecessary testing
  – Direct cost savings of $133 for test cancellation

• Identified issue with missing labs

• Contributed to timely patient diagnosis
  – Unknown indirect cost savings for reducing time to correct diagnosis
Case #3- Diagnostic Management Intervention

Encounters received through direct case management requests to the clinical laboratory

Patient:

- 47 year old female, HIV+
- PMH:
  - 2 weeks prior, patient transported to ED by EMS
  - Complaint of non-witnessed seizure
  - Home glucometer reading of 32 mg/dL

- No symptoms documented by EMS or ED
  - CBC within reference ranges, except hemoglobin 10.4 g/dL ↓
  - BMP within reference ranges
  - Repeated POCT glucose: 76-94 mg/dL
Case #3

ED referred patient to endocrinology for evaluation for hypoglycemia

- Endocrinology admitted patient for a 72 hour fast with:
  - Renal profile & CBC on admission
  - Renal profile every 8 hours
  - POCT glucose measured every 2-4 hours
  - Every 6 hours -
    - Plasma glucose
    - Insulin
    - Proinsulin
    - C-peptide
    - Beta-hydroxybutyrate
Case #3

What initiated the Diagnostic Management Consultation?

Biohazard bag sent via tube system...........

- Contained specimens collected over the 72-hour fasting episode
Case #3

Admissions Lab Test Results:
• All renal profiles were within reference range limits.
• CBC in reference range, except hemoglobin of 10.0 g/dL ↓

Lab Results During the 72 hr. Fasting:
• All POCT glucose results ranged 74-109 mg/dL
• All serum glucose results ranged from 83-99 mg/dL
Case #3

DCLS resident performed initial chart review:

- Computer Program Order Entry (CPOE) procedures not followed

- Samples sent at the same time were unspun and beyond acceptable specimen stability

- DCLS notified ordering physician explaining why test orders were cancelled
Case #3

Attending Physician Response:

“It is recommended by the Mayo clinic and the endocrine society hypoglycemia guidelines 2009 that hypoglycemic labs (insulin, proinsulin etc.) be drawn every 6 hours while a patient is undergoing a 72 hour fast in house. This is the standard of care.”
Case #3

Initiation of Diagnostic Management Team (DMT)

DMT Members:
• Pathologist
• Pathology Resident
• Laboratory Department Manager
• DCLS Resident
• Medical Librarian
Case #3

DCLS requested Medical Librarian to search for the guideline cited by physician

Guideline states patients should undergo 72-hour fast if:

- Exhibit Whipple’s Triad
  - Signs & symptoms consistent with hypoglycemia
  - Low plasma glucose concentration
  - Documentation of symptom resolution after plasma glucose is raised
  - “drugs, critical illnesses, hormone deficiencies, and non-islet cell tumors” have been evaluated first
Case #3

DMT concluded:

• Guideline did not apply to this patient
• Whipple’s triad criteria was not met
• Entire admission was not medically necessary
• No follow-up on anemic patient that had 96 tubes of blood drawn

Outcome – Policy Change……..

Pathologist contacted patient’s physician & Medical Director of Endocrinology:

• All future admissions for 72 hr. inpatient fasting hypoglycemia protocol must have pathology approval prior to admission
Case #4
Diagnostic Management Intervention

Patient:
- 14-week-old male, born by c-section
- Mom checked on infant in his crib in the middle of night
- Noticed something was “off”
- Spontaneous subdural hemorrhage
- Outside hospital transferred baby under suspicion of shaken baby syndrome
- Social Service and Child Protective Services assigned to infant
Case #4

Resident physician contacted DCLS resident requesting assistance:

- States family doesn’t fit the profile for child abuse
- Asked……..
  - What coagulopathies could explain infant’s presentation?
  - Which tests to order with minimal blood volume due to bleeding?

- Patient going to neurosurgery now
  - Will likely need blood transfusion later in day
Case #4

Emergency DMT activated…………………

Team members:
• Pathologist
• Pathology Resident
• DCLS Resident
• Hematology/Coagulation Manager
Case #4

Team reviewed :
- Available medical records & limited family history
- Listed non-trauma differential diagnoses
- Diagnoses ranked most probable to least probable

Testing prioritized
- Limited volume available to test
- Transfusion would make further testing not accurate

• Patient specific testing algorithm was agreed upon
• DCLS Resident coordinated testing with PICU patient care team
Case #4

Laboratory test results:

<table>
<thead>
<tr>
<th>Test</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Testing</td>
<td></td>
</tr>
<tr>
<td>PT</td>
<td>10.9 sec</td>
</tr>
<tr>
<td>PTT</td>
<td>74.8 sec. ↑↑</td>
</tr>
<tr>
<td>2nd Level of Testing</td>
<td></td>
</tr>
<tr>
<td>Factor VIII activity</td>
<td>&lt;1% ↓ ↓ ↓ ↓</td>
</tr>
<tr>
<td>Factor IX activity</td>
<td>44%</td>
</tr>
<tr>
<td>3rd Level of Testing</td>
<td></td>
</tr>
<tr>
<td>vWF antigen</td>
<td>73%</td>
</tr>
</tbody>
</table>

Diagnosis: Severe Hemophilia A

- Diagnosis obtained within 5 hours of baby leaving the OR
- Sufficient diagnostic information obtained to stabilize & treat appropriately
Case #4

- Pathologist contacted Child Protective Services and Social Worker
- DCLS resident contacted with patient care team

Both communicated:
- This was an inherited condition of most severe form
- Spontaneous bleeding common in first year with severe hemophilia A
- Life-time treatment regimen will be necessary
- Bleeding episodes still likely to occur
- Genetic testing at a later date (outpatient)
Case #4

DMT Consultation Outcomes:

• Rapid accurate diagnosis obtained with minimal testing

• Correct patient management initiated in a timely manner

• Prevented a child from entering foster care unnecessarily

• Prevented false charges of child abuse against a parent
Cost Savings Outcomes

• Total cost savings from DCLS consultations during clinical residency:
  – $628,493 over 9 ½ months (documented)

• Total cost savings from DCLS consultation during clinical practice:
  – $1.6 million (documented)
DCLS Consultations

Contribute to:
• Improve time to correct diagnosis
• Decrease inappropriate test ordering
• Increase correct test interpretation
• Improve patient safety
• Decrease healthcare costs

Quality improvement
• Patient care & safety
• Patient outcomes
• Utilization of laboratory services
Requests from medical staff & health system administrative leadership

- Increase physician continuing education in lab medicine
  - Teach in Grand Rounds regularly for many specialty services
  - Teach weekly in Family Medicine

- Expand patient rounding team consultation

- Institute health system-wide pathology utilization program

- Work with Revenue Integrity to resolve billing and revenue issues
  - Increased pathology charges by $5.5 million per year

- Work with IT to resolve pathology data & quality reporting to Vizient
Additional Projects

- Implement and oversee Diagnostic Management Teams

- Oversee resident-driven research in service-specific utilization and algorithm development:
  - 7 Family Medicine
  - 2 Internal Medicine
  - 2 Pediatrics
  - 2 Pharmacy fellows
  - 1 Pathology
  - 1 Psychiatry
  - 2 summer medical student researchers

- Developed 2 grant proposals
  - Improving pathology service delivery
  - Clinical outcomes in transgender patients
New healthcare model - Change in delivery of lab services

DCLS: Dedicated to increasing the value of diagnostics through:
- Consultation as members of interprofessional healthcare teams
- Conduct research focused on evidence of the impact of diagnostics on healthcare outcomes
THANK YOU
References

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27. Taylor, JR., et al. (2017). Opportunities to Enhance Laboratory Professionals’ Role On the Diagnostic Team. Laboratory Medicine, Volume 48, Issue 1, 97-103.
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