



Challenges and Opportunities for the Medical Director Leading a Clinical Laboratory in the 21st Century

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Learning Objectives

- 1) Identify challenges that clinical laboratories presently face.**
- 2) Recognize the opportunities available to medical leadership to overcome the challenges and lead to success.**

Major Trends in Healthcare

- **Pressure to reduce health care costs**
 - Changing payment models and reduced reimbursement
- **Paradigm shift in health care delivery**
 - Shift from sickness to wellness
- **Increasing demand for pathology services**
 - Changing demographics - aging baby boomers
 - Need for lab results interpretation management
- **Optimization of test utilization**

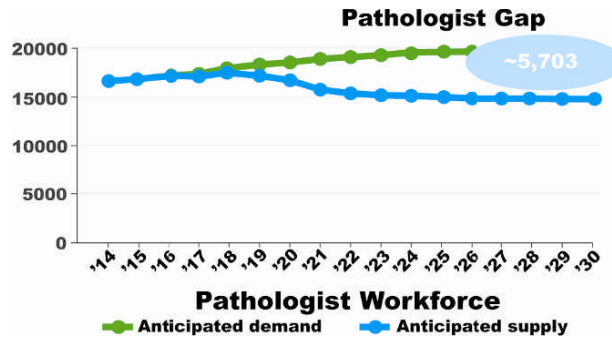
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Emergence of New and Enhanced Services

- **Precision/genomic medicine**
- **Bioinformatics and information technology**
- **Biorepository management**
- **In vivo microscopy**

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Decreasing Pool of Pathologists



Robboy, S. J., S. Weintraub, et al. (2013). "Pathologist Workforce in the United States: I. Development of a Predictive Model to Examine Factors Influencing Supply." *Archives of Pathology & Laboratory Medicine* 137(12): 1723-1733.

Decreasing Pool of Med Techs



Other Challenges for Clinical Labs

- Need to keep up with the technological advances and information technology
- There is increase demand for more complex testing with less resources
- Learn to utilize the resources that are available and shift our culture to more efficient utilization of the resources at our disposal

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Role of the Medical Director

- Responsible for the overall operation and administration of the laboratory including employment of personnel who are competent to perform test procedures; record and report test results accurately and proficiently; and assure compliance with the applicable State and Federal regulations

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Medical Director Job Description, CLIA' 88

1. Learn CLIA (www.cms.hhs.gov/clia); understand the laboratory director delegations and monitor them.
2. Review policies, procedures and processes; i.e., their quality system.
3. Review problem log and corresponding corrective actions. Learn from your/their mistakes.
4. Are the laboratory's panic values appropriate for the patient population?
5. Notify the State Department of Health and the accrediting organization, if applicable, of the change in laboratory director.
6. Review and evaluate the laboratory's quality assessment plan, indicators and monitor.
7. Review the laboratory's proficiency testing (PT) enrollment and performance, corrective actions for all missed challenges and speak to the staff about what constitutes intentional referral of PT.
8. Learn what equipment and test systems are used in the laboratory, the QC and validation protocols utilized.
9. Understand the supervisory and testing personnel array for the laboratory; confirm their training and competency record and that there are adequate numbers of the right personnel for each discipline.
10. Ensure that the laboratory is customer focused.



Management is About Human Beings

“The task of the management is to make people capable of joint performance, to make their strengths effective and their weaknesses irrelevant”

Peter Drucker

The Medical Director's attention needs to focus on the management of human beings along with scientific and medical expertise

We are not Alone as Managers

- For a laboratory to be successful, there is need to align the administrative structure with the medical function
- Need for flow of information, common goals and cooperation between the **Lab Administration** and **Medical Leadership**
- The biggest asset of the medical director is the **team of pathologists and laboratory scientists** he/she leads

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Silos

Medical Director

- Responsible for the overall operation and administration of the lab
 - Employment of personnel who are competent to perform test procedures; accurate test results and reporting
 - Assure compliance with the applicable State and Federal regulations
- QI/QA plan
 - Proficiency testing
- Set standards of practice
- Pathologists' performance evaluation
- Maintain laboratory licensure
- Liaison with clinical services
- Professional & Scientific leadership

Lab Administrator

- Ensure operational efficiency
 - Formulate objectives and develop action plan
- Manage fiscal resources
 - Budget; capital information
- Manage human resources
 - Hiring and retention of qualified workers for all positions
 - Performance evaluations
 - Staff meetings
- Provide safe work environment
- Liaison with other hospital departments



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MEDICAL DIRECTOR



- Responsible for the overall operation and administration of the lab
- Set standards of practice
- Pathologists' performance evaluation
- Maintain laboratory licensure
- Liaison with clinical services
- Professional & Scientific leadership

Shared Leadership

- Vision & Mission
- Goal
- Develop budget/capital
- QI/QA
- Oversee new test development
- Policy/procedures
- Regulatory/Compliance
- Lab Accreditation
- Human resources
- Develop and maintain cycle of accountability
- Staff meetings

LAB ADMINISTRATOR

- Ensure operational efficiency
- Manage fiscal resources
- Manage human resources
 - Hiring and retention of qualified workers for all positions
 - Performance evaluations
- Provide safe work environment
- Liaison with other hospital departments

Medical Director as a Driver

- Bring knowledge and innovation so that the available resources can be utilized more efficiently
- Improve lab operation efficiency by implementing LEAN and six sigma processes
- Expand the role of the pathologists in providing and clinical pathology consultation and patient specific narrative interpretation

Optimization in Test Utilization

- Eliminate unnecessary testing or testing with questionable clinical utility will reduce costs
- Expand the test menu and implement new lab tests that focus on wellness
- Pathologists and lab scientists must play key role in educating clinicians and other health care professionals of appropriate test utilization

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Transformation to 21st Century Lab

- The Medical Director's contribution to the health care will be much greater if he/she starts asking hard questions that require rigorous thinking and pushing the limits
- To be successful, the Medical Director needs to apply more than just a few more leadership techniques, he/she needs to build a leadership team of pathologists
- The role of the pathologist needs to broaden from individual case diagnoses also to become a leader and advisor to the clinical staff and other staff providing health care
- We need to invest in formal leadership development programs for pathologists

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