

**LABORATORY  
ACCREDITATION AND THE  
CULTURE OF QUALITY IN  
THE MIDDLE EAST**

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**Lab Accreditation Program**

# Who Seeks Accreditation?

- **Schools**
- **Colleges**
- **Universities**
- **Hospitals**
- **Medical Laboratories**
- **Blood Banks**
- **Public Health Facilities**
- **Industries**
- **Etc..**

# What is Accreditation?

- **Thesaurus:** Accreditation is the act of granting credit or recognition.
- **The Free Dictionary:** The act of accrediting or the state of being accredited, especially the granting of approval to an institution of learning by an official review board after the school has met specific requirements.

# What is Accreditation?

- **Mosby's Medical Dictionary:** Accreditation is a process whereby a professional association or non-governmental agency grants **recognition** to a school or health care institution for demonstrated ability to meet predetermined criteria for established standards, such as the accreditation of hospitals by the Joint Commission on Accreditation of Healthcare Organizations or of schools of nursing by the NLNAC.

# What is Accreditation?

- **Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health: Accreditation is a process that a health care institution, provider, or program undergoes to demonstrate compliance with standards developed by an official agency.**
- **Medical Dictionary for the Health Professions and Nursing: Approval, certification, or endorsement by an authority.**

# What is Accreditation?

- **United Kingdom Accreditation Service (UKAS):**  
**Accreditation is a formal, third party recognition of competence to perform specific tasks.**
- **Usually the reason for getting something independently evaluated is to confirm it meets specific requirements in order to reduce risks.**
- **Anything or anyone can be evaluated - products, equipment, people, management systems or organizations.**

# Accreditation then means:

- **Recognition.**
- **Approval.**
- **Certification.**
- **Stamp of Dependability.**
- **Compliance with preset standards.**
- **Endorsement by a known authority in the field.**
- **Meeting requirements to reduce risk.**

# Why Accreditation?

- **A recognition of testing competence.**
- **A benchmark for performance.**
- **A marketing advantage.**
- **International recognition for your laboratory.**

# Why Accreditation?

- A recognition of testing competence:

**Laboratory accreditation is a means of determining the technical competence of laboratories to perform specific types of testing, measurement and calibration.**

**It also provides formal recognition to competent laboratories, thus providing a ready means for customers to identify and select reliable testing, measurement and calibration services able to meet their needs.**

# Why Accreditation?

- **A benchmark for performance:**

**Laboratory accreditation benefits laboratories by allowing them to determine whether they are performing their work correctly and to appropriate standards, and provides them with a benchmark for maintaining that competence.**

**A regular assessment by an accreditation body checks all aspects of a facility's operations related to consistently producing accurate and dependable data. Areas for improvement are identified and discussed.**

# Why Accreditation?

- **A marketing advantage:**

**Accreditation is an effective marketing tool for testing, calibration and measurement organizations, and a passport to submit tenders to contractors that require independently verified laboratories.**

**Laboratory accreditation is highly regarded both nationally and internationally as a reliable indicator of technical competence.**

# Why Accreditation?

- **International recognition for your laboratory:**

**Many countries around the world have one or more organizations responsible for the accreditation of their nation's laboratories. Most of these accreditation bodies have now adopted ISO/IEC 17025 as the basis for accrediting their country's testing and calibration laboratories, or ISO 15189 for medical laboratories.**

# The Journey to Accreditation

- **Financing**
- **Infrastructure and Physical Facilities**
- **Human Resources**
- **Supplies and Equipment**
- **Quality Assurance**
- **Quality Improvement**
- **Safety**
- **Educating Clients**
- **Maintaining the Standard**

# Quality Assurance

- **A program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met.**
- **It can also be defined as the systematic measurement, comparison with a standard, monitoring of processes and an associated feedback loop that confers error prevention**

# ELEMENTS OF QUALITY ASSURANCE

- **Training staff to establish and interpret QC data.**
- **Sample type, acceptance/rejection of samples, sample preparation.**
- **Daily QC runs with clinically relevant control levels; must be accepted before patient samples processed.**
- **With new lots of QC material, internal target values must be established .**
- **QC data analysis – Levy-Jennings graphs, Westgard rules.**

# ELEMENTS OF QUALITY ASSURANCE

- **Daily maintenance, housekeeping**
- **Inter-laboratory comparisons**
- **External proficiency program**
- **Acceptance of QC results (external & internal) by Lab Director and Lab Supervisor**
- **Policy for (exception) QC results**
- **Maintaining published turnaround times**
- **Accurate transcription of results**
- **Security and confidentiality of lab data and records**

# Quality Improvement

- **It is the combined and unceasing efforts of everyone: healthcare professionals, patients and their families, researchers, payers, planners and educators, to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning).**

# What is the “Culture” of an institution?

- The culture of an organization is the embodiment of the core values, guiding principles, behaviors, and attitudes that collectively contribute to its daily operations.
- Organizational culture is the very essence of how work is accomplished; it matures over several years, during which norms are passed on from one “generation” of staff to the next.

# FOUNDATIONAL ELEMENTS OF QI CULTURE

- **Leadership Commitment:**

**Senior leadership's commitment is vital for the success and sustainability of a QI culture.**

**The health director and senior management should initiate and lead the process for transformational change, dedicate financial and human resources to QI, communicate progress, and exhibit lasting support for QI.**

# FOUNDATIONAL ELEMENTS OF QI CULTURE

- **QI Infrastructure:**

**To build a culture of QI, infrastructure must be in place to ensure that QI efforts are aligned with the organization's mission, vision, and strategic direction and that QI is linked to organizational performance.**

**The following are components of a strong QI infrastructure:**

- **Performance Management System.**
- **Performance management committee or QI Council (PM/QI Council).**
- **QI Plan**

# FOUNDATIONAL ELEMENTS OF QI CULTURE

- **Employee Empowerment and Commitment:**  
When a QI culture is achieved, all employees, from senior leadership to frontline staff, have infused QI into the way they do business daily. Employees continuously consider how processes can be improved, and innovation is the norm.

QI is no longer seen as an additional task but a frame of mind in which the application of QI is second nature.

# FOUNDATIONAL ELEMENTS OF QI CULTURE

- **Customer Focus.**
- **Teamwork and Collaboration**
- **Continuous Process Improvement**

# The Roadmap to the Culture of Quality Improvement

- **Phase 1: No Knowledge of QI:**

**In this phase, LHD staff and leadership are unaware of QI and its importance. QI is not considered as a way of doing business, evidence base is not used in decision-making, and a reactive rather than proactive approach is used to address problems.**

# The Roadmap to the Culture of Quality Improvement

- **Phase 2: Not Involved with QI Activities:**

**In this phase, leadership understands and discusses QI with staff but does not enforce the implementation of or dedicate sufficient staff time and resources for QI.**

# The Roadmap to the Culture of Quality Improvement

- **Phase 3: Informal or Ad Hoc QI activities:**

**Discrete QI efforts are practiced in isolated instances throughout the LHD, often without consistent use of data or alignment with the steps in a formal QI process.**

# The Roadmap to the Culture of Quality Improvement

- **Phase 4: Formal QI Activities Implemented in Specific Areas:**

**Following adoption of one or more formal QI models, QI is being implemented in specific program areas, but QI is not yet incorporated into an organization-wide culture.**

# The Roadmap to the Culture of Quality Improvement

- **Phase 5: Formal Agency-Wide QI:**

**QI is integrated into the agency strategic and operational plans. PM/QI Council oversees the implementation of a detailed plan to ensure QI throughout the LHD. Policies and procedures are in place and data are commonly used for problem-solving and decision-making.**

# The Roadmap to the Culture of Quality Improvement

- **Phase 6: QI Culture:**
- **QI is fully embedded into the way the agency does business, across all levels, departments, and programs.**

**Leadership and staff are fully committed to quality, and results of QI efforts are communicated internally and externally.**

**Even if leadership changes, the basics of QI are so ingrained in staff that they seek out the root cause of problems.**

**They do not assume that an intervention will be effective, but rather they establish and quantify progress toward measurable objectives.**

# Models of QI

- **FADE** - There are 4 broad steps to the FADE QI model:
  - **Focus:** Define and verify the process to be improved.
  - **Analyze:** Collect and analyze data to establish baselines, identify root causes and point toward possible solutions.
  - **Develop:** Based on the data, develop action plans for improvement, including implementation, communication, and measuring/monitoring.
  - **Execute and Execute:** Implement the action plans, on a pilot basis, and Install an ongoing measuring/monitoring (process control) system to ensure success.

# Models of QI

- **PDSA - The 4 steps in this model include:**
  - **Plan: Plan a change or test of how something works.**
  - **Do: Carry out the plan.**
  - **Study: Look at the results. What did you discover?**
  - **Act: Decide what actions should be taken to improve.**

# So we have QI: What are the aims?

## Institute of Medicine Six Aims for QI

- **Safe: avoiding injuries to patients from the care that is intended to help them.**
- **Effective: providing services based on scientific knowledge to all who could benefit, and refraining from providing services to those not likely to benefit.**
- **Patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.**

# So we have QI: What are the aims?

- **Timely:** reducing waits and sometimes harmful delays for both those who receive and those who give care.
- **Efficient:** avoiding waste, including waste of equipment, supplies, ideas, and energy.
- **Equitable:** providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

# QI: What is it for me?

- **Confidence in your results.**
- **Prestige of belonging to a lab with high standards.**
- **Sense of Professionalism.**
- **Better chances for future hiring.**

# The CAP LAP Mission

The CAP Laboratory Accreditation Program **improves patient safety by advancing the quality of pathology and laboratory service** through education, standard setting, and ensuring laboratories meet or exceed regulatory requirements.

# CAP LAP Philosophy

- **Promote a Culture of Quality**
  - Quality control
  - Performance improvement
  - Proficiency testing
- **Regulatory role**
  - Assess compliance with CAP requirements, including CLIA-88 regulations

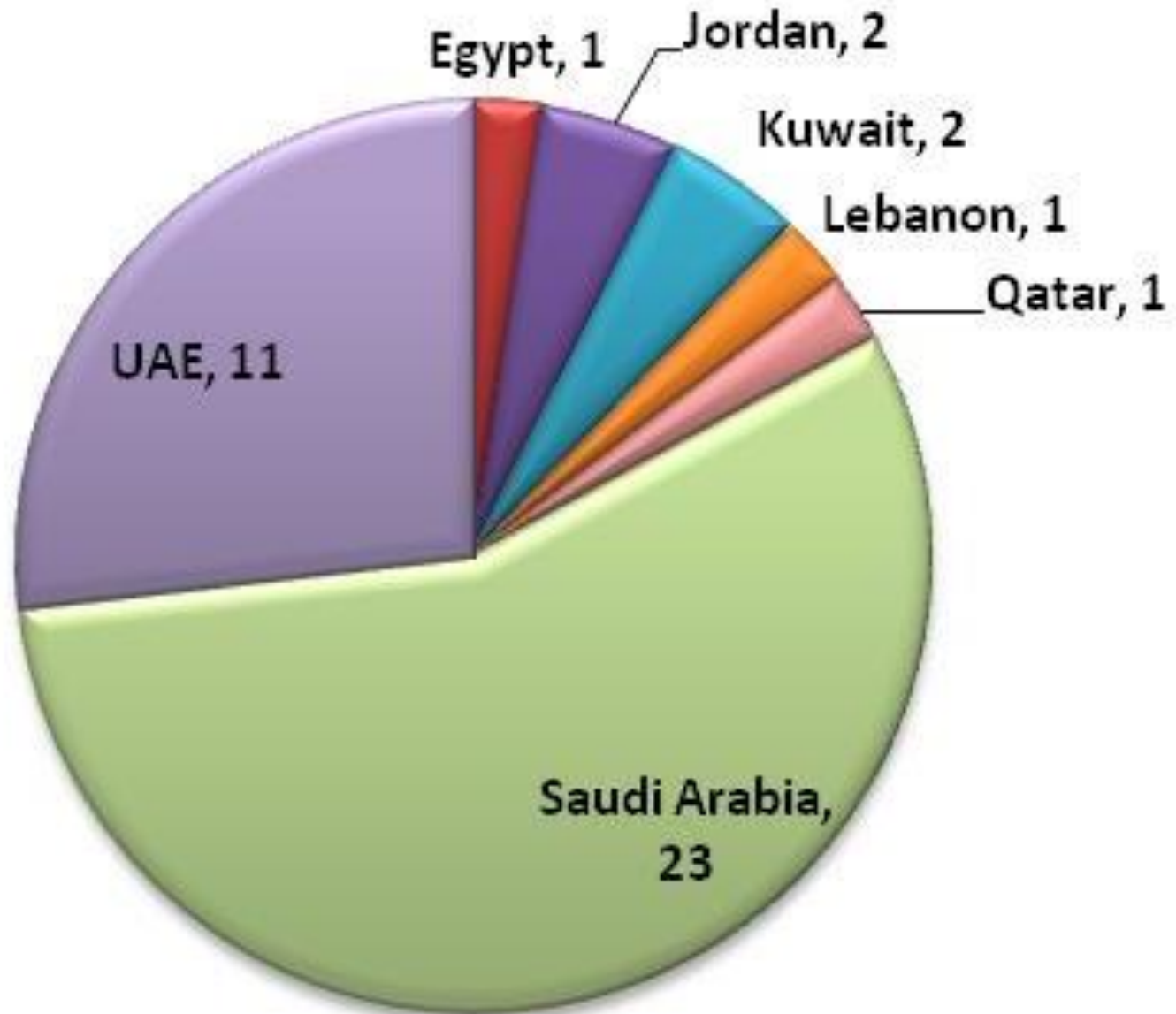
# **History of CAP Laboratory Accreditation Program**

- **In Existence Since 1961**
- **Progressive Growth**
- **Relationships with other  
Organizations**

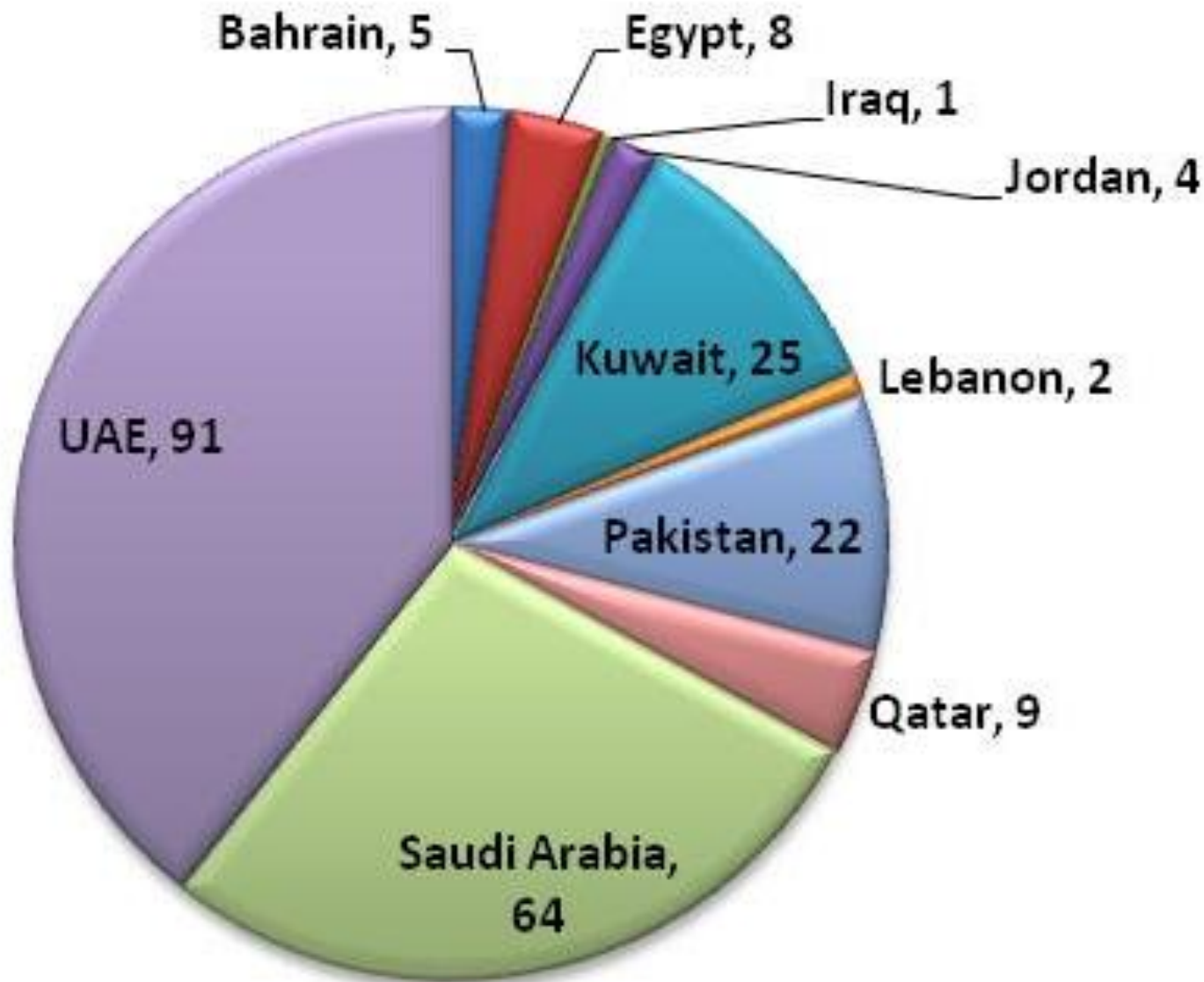
# **CAP Laboratory Accreditation Program**

- **Over 7,000 Participating Laboratories.**
- **Ten to Twelve Inspections per Day.**
- **Worldwide Recognition**
  - **210 Civilian International labs.**
  - **70 US Military Labs Overseas.**
  - **45 Countries including eight Arab countries: Saudi Arabia, UAE, Kuwait, Qatar, Jordan, Lebanon, Egypt, and Iraq.**

# Total CAP Accredited Labs in the Middle East



# Total Middle East Labs Participating in CAP Proficiency Testing





**KING FAISAL SPECIALIST HOSPITAL  
AND RESEARCH CENTER  
Riyadh, Saudi Arabia**



**DHAHRAN HEALTH CENTER**  
Dhahran, Saudi Arabia



3:17:00



**THE AMERICAN HOSPITAL OF DUBAI**  
Dubai, United Arab Emirates

# **US State Department Restrictions on Travel to Middle East**

- **Early 2000s: Terrorist attacks in Saudi Arabia, and the beginning of wars in Afghanistan and Iraq**
  - **Middle East designated as a dangerous area according US State Department**
  - **US inspectors not allowed to travel to most areas of the Middle East**



# **In-Country Inspectors and Growth in Participation**

- **2003 and after: Trained local inspectors and team leaders; utilize local inspectors for Middle East inspections**
- **2004: The AUB Medical Center, Lebanon**
- **2007: Two private labs in Kuwait**
- **2009: The King Hussein Cancer Center, Jordan**



**AMERICAN UNIVERSITY OF BEIRUT MEDICAL CENTER**  
**Beirut, Lebanon**



**KING HUSSEIN CANCER CENTER**  
Amman, Jordan

# Goal of CAP Inspection

**Quality Improvement, accomplished by:**

- **Educational process.**
- **Peer review.**
- **It is an opportunity for improvement.**

# LAP Inspection: Maintaining Balance



**Education**

**Quality  
Improvement**

**Regulatory  
Compliance**

# Standards and Checklists

- **Purposes:**
  - **Standards are the broad principles the laboratory must meet in order to achieve accreditation**
  - **Checklists provide detailed requirements that inspectors use to determine whether laboratories meet the Standards**

# The Standards for Laboratory Accreditation

- **Standard I Director**
- **Standard II Physical Facilities & Safety**
- **Standard III Quality Control and  
Performance Improvement**
- **Standard IV Inspection Requirements**

# Documentation is Key

**If it isn't:**

- **Written down**
- **Reviewed and**
- **Signed**

**It isn't happening !!**



# Famous Last Words

**“Oh yes, we do all of that stuff.....(I think.)”**

**Dr. I. M. Complacent,  
Medical Director  
Mediocre Laboratories, USA**

# CONCLUSIONS

- **There is a widespread awareness of the importance of QI/QA and accreditation in the Middle East.**
- **Implementation can be problematic due to lack of support from leadership, cost, need for manpower, need for space for the lab, and the need for documentation with lots of paper work.**
- **Resistance to change and complacency or lack of motivation are important factors hindering implementation of QI/QA or accreditation.**