

Review

Overview of the laboratory accreditation programme of the College of American Pathologists

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SUMMARY Although Saudi medical laboratories have developed enormously over the past 25 years, the absence of a national body for medical laboratory accreditation has meant the number of accredited laboratories (seven) remains low. Of these, five are accredited by the College of American Pathologists' Laboratory Accreditation Program (LAP)—the 'gold standard' of laboratory accreditation. It requires successful performance in the College of American Pathologists' proficiency testing programme as well as passing on-site inspections carried out by practising laboratory technicians, after which the laboratory is accredited for a 2-year period. This article gives an insight into the current situation of laboratory accreditation in Saudi Arabia and an updated overview of the process involved in obtaining laboratory accreditation from the College of American Pathologists.

Introduction

The Saudi Arabian health system has developed enormously over the past 25 years. The medical laboratory services, which are vital to any health care facility, constantly strive to provide the public with reliable laboratory data of the highest possible standard. This is usually demonstrated first through participation in high standard quality assurance and quality control programmes, and secondly by obtaining laboratory accreditation. In the absence of a national quality assurance programme, hospitals and laboratories—government and private sector—are currently participating in different international quality assurance programmes for medical laboratories.

These quality assurance programmes vary between different laboratories and currently include the following:

- the Middle East External Quality Assurance Scheme (MEEQAS), implemented in several Ministry of Health laboratories;
- proficiency testing programmes offered by the College of American Pathologists (CAP);
- the Quality Assurance Programme of the Royal College of Pathologists of Australia (RCPA);
- the United Kingdom National External Quality Assurance Scheme (NEQAS);
- the Centers for Disease Control and Prevention (CDC) programme to monitor antibiotic susceptibility testing; and
- joint collaborative study quality assurance programmes.

The positive effects of accreditation schemes on the setting of quality specifica-

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tions by laboratories cannot be ignored. However, despite the participation of many laboratories in international quality assurance/control programmes, the number of accredited laboratories in Saudi Arabia remains low [1]. This may be due to the absence of a national body for medical laboratory accreditation and hence the need to seek accreditation elsewhere and the associated difficulties of doing so.

One of the international accreditation programmes highly regarded among medical laboratories in Saudi Arabia is the Laboratory Accreditation Program (LAP), offered by the College of American Pathologists (CAP). The LAP is widely recognized as the 'gold standard' of laboratory accreditation programmes and has served as a model for various accreditation programmes throughout the world. Certainly, several United States of America government regulatory agencies (e.g. the Health Care Financing Agency) and private agencies (e.g. the Joint Commission on Accreditation of Health Care Organizations) accept the LAP in place of their own programmes for laboratory accreditation [2,3].

The LAP examines all aspects of quality control and quality improvement in the laboratory, including testing methodologies, reagents, control media, equipment, specimen handling, procedure manuals, test reporting and internal and external proficiency testing and monitoring. In addition, the LAP monitors all aspects related to personnel, safety and overall management practices.

The LAP uses an educational, peer-review inspection process, which allows any laboratory to be inspected by knowledgeable working professionals with up-to-date knowledge of the changing needs of the laboratory community. This serves the purpose of adding an educational experience to the inspection process and allows

both the inspectors and the laboratory staff to share their knowledge and expertise. This high level of test quality ensures that the laboratory provides the best possible care—an ethical obligation by which it is bound—to the patient community it serves.

The objective of this overview is to aid national and regional health care organizations considering laboratory accreditation through CAP by providing them with up-to-date concise information about the process of accreditation. This may also help provide some understanding of the process of accreditation by other accreditation bodies, as these processes are usually similar.

Sources

The sources used for this overview included a systematic review of up-to-date CAP accreditation documentation, the CAP website, standards for laboratory accreditation, and literature reviews of papers written about the CAP accreditation process. All possible sources of information were sought regarding the status of laboratory accreditation in Saudi Arabia, including local archives, literature reviews, the Internet and personal communications.

Accreditation bodies

There are currently seven medical laboratories accredited in Saudi Arabia, six of which are medical laboratories based in government-run hospitals and one in a private hospital. These laboratories are accredited by different organizations, five of them by the CAP. The Department of Pathology and Laboratory Medicine at the King Faisal Specialist Hospital was the first to acquire CAP accreditation in 1984; this was followed by the Department of Pathology and Laboratory Medicine at the King

Fahad National Guard Hospital, the Dhahran Health Centre, the Al-Hada Armed Forces Hospital, and most recently, the clinical laboratories at the Saudi Aramco Dhahran Health Centre achieved accreditation with distinction.

Steps in the CAP accreditation process

The steps in the CAP accreditation process [4-7] can be summarized as follow:

1. Application submitted by laboratory to CAP

The laboratory submits an application request form together with a US\$ 500.00 deposit to the CAP central office. (If the laboratory receives accreditation, the deposit is applied to the first year's accreditation fees.)

2. Application package forwarded by the CAP

The CAP forwards an application package to the laboratory, containing the following:

- a copy of the *Laboratory Accreditation Manual*;
- instructions for the completion of the accreditation materials;
- the accreditation application, including: addresses, laboratory contacts, licensure and certification, release of data, conditions of accreditation, personnel qualification form and laboratory sections to be duplicated and completed for each section of the laboratory);
- a master activity manual;
- a complete set of inspection checklists; and
- the standards for laboratory accreditation.

3. Laboratory completes the application and checklist review

The CAP Commission on Laboratory Accreditation (CLA) expects that the laboratory will have met the standards by the date the application materials are returned to the CAP. A new applicant to the accreditation programme has 6 months to complete and return the application materials.

4. CAP application review

CAP central office reviews the application for accuracy and completeness before a laboratory is accepted for the accreditation programme. Additional information may be requested. An inspector will be assigned when all materials are received.

5. Inspection team assembled

The CLA regional commissioner recruits a team leader and notifies the CAP central office. The team leader leads and oversees the on-site inspection and assembles the inspection team appropriate for the size and scope of the laboratory. The team leader is usually a qualified pathologist, preferably a fellow of the CAP, associated with a CAP accredited laboratory, appropriately trained in the inspection process and desirably a peer of the medical director of the laboratory being inspected in terms of professional status, size and type of practice. A non-pathologist team leader with experience in a specialty area, such as cytogenetics, may serve with the prior agreement of the laboratory director and regional commissioner.

6. Inspection date agreed

The team leader will call the laboratory director and set a mutually agreed inspection date. It is important to note that the inspection date is scheduled at the convenience of the inspector. The team leader then calls the

CAP central office to report the inspection date.

7. Inspection date preliminaries

The team leader and the inspectors arrive on the designated date. Before the inspection process begins, the team will meet with the laboratory director to determine whether or not the director has sufficient responsibility and authority for the day-to-day operations of the areas to be inspected.

8. Inspection

Once it is established that the director has effective authority over the operations to be inspected, the inspection process commences, with the sequential performance of the following:

- a) a meeting is held with the laboratory supervisor at the beginning of the day;
- b) team members are introduced to each other and allowed to become acquainted;
- c) a tour of the laboratory is taken and conditions noted, especially cleanliness and safety violations;
- d) the laboratory's procedure manuals and proficiency testing results are reviewed;
- e) specific items, such as the quality of smears and stains, adherence to safety policies, reagent labelling and patient reports are directly observed;
- f) a thorough safety inspection of each department is carried out;
- g) quality assurance and quality control documentation [8] are reviewed;
- h) the Quality Improvement Plan [9] is revised;
- i) the physical space is checked and any space deficiencies noted; and
- j) the inspection findings are reviewed with the team leader before a summation conference.

9. Summation conference

Immediately following the inspection, a summation conference takes place to review deficiencies and positive findings with the laboratory director, supervisors and as many of the technical staff as feasible. The team leader will allow the laboratory to correct deficiencies, if possible, prior to the departure of the inspection team.

10. Inspection summation report

At the end of the summation conference, the team leader will issue the inspector summation report (ISR). The ISR consists of two parts:

- Part A, which will be sent to the CAP central office, contains a general summary of the inspection and inspector's comments about the laboratory; and
- Part B, which is given to the laboratory director at the end of the inspection process, lists deficiencies found during the inspection and the inspector's recommendations. If the laboratory is able to correct deficiencies cited immediately, then these deficiencies will not be reported to the CAP central office.

The inspector leaves a copy of Part B of the ISR with the director, but not part A. Part A of the ISR is confidential and will be sent to the CAP central office together with the original copy of Part B.

11. Laboratory response and corrective action

The laboratory has 30 days from the inspection date to respond to the CAP central office, with documentation of corrective action taken to rectify deficiencies.

12. Laboratory accreditation

The laboratory is accredited for a 2-year period, but conducts a self-inspection after the first 12 months. Accreditation is valid for a 2-year period from the date of the

first inspection, and is renewable every 2 years on the accreditation anniversary date. During the second year of the 2-year accreditation cycle, laboratories complete a mandatory self-evaluation. Checklists are sent to the laboratory for completion of self-inspection and this form must be returned within 30 days of receiving the self-evaluation materials.

CAP proficiency testing

Proficiency testing involves the performance of test procedures on common samples by multiple participating laboratories. The samples are usually sent to the participating laboratories every quarter, with subsequent centralized tabulation of each laboratory's results. Regulatory requirements are fulfilled when the laboratory obtains acceptable results.

Laboratories must participate regularly in a CAP-approved proficiency testing programme for each patient-reportable analyte, whenever an appropriate programme is available. Each separately accredited laboratory must be enrolled in such a programme under its own CAP number.

It is preferable that the laboratory has a performance history of one or two shipments of proficiency testing before an initial inspection. If proficiency testing for an analyte is not commercially available, is not formally graded, or is not compatible with all methods, the laboratory is still required to perform some type of external, alternative or comparative testing at least every 6 months. This may be accomplished through blind testing of specimens with known results, exchange of specimens with other laboratories, or other equivalent systems specifically recommended and approved by the laboratory director. Proficiency testing samples should be rotated

among the laboratory personnel who perform routine testing [10,11].

Currently the CAP runs two proficiency testing programmes, Excel and Survey.

Excel

This programme is available for the physician's office and other small laboratories and covers the following disciplines:

- clinical chemistry;
- haematology;
- urinalysis and clinical microscopy;
- coagulation;
- microbiology;
- immunology;
- transfusion medicine; and
- multidiscipline combination series.

Survey

This is a more comprehensive proficiency-testing programme than Excel. The programme was designed to cover a wide range of laboratory disciplines. It currently includes the following disciplines:

- general chemistry and special chemistry;
- therapeutic drug monitoring;
- endocrinology;
- blood gas and oximetry;
- toxicology;
- calibration verification/linearity and instrumentation;
- haematology and clinical microscopy;
- coagulation;
- microbiology;
- transfusion medicine;
- transfusion-transmitted viruses;
- parentage testing;
- immunology;
- flow cytometry and quantitative image analysis;

- histocompatibility;
- cytogenetics;
- molecular genetics;
- anatomic pathology; and
- forensic sciences.

Basic combinations of the programmes are available, designed to suit the individual needs of certain laboratories.

Checklists

Checklists are detailed series of questions designed to implement CAP laboratory accreditation standards [6]. Their current format permits comprehensive evaluation of different clinical laboratory disciplines. During the inspection, checklist questions are used by the inspectors to evaluate whether or not a laboratory meets the LAP standards (e.g. for molecular pathology laboratories, the general and molecular pathology checklists are relevant).

The checklists are organized according to specific laboratory disciplines. Each of these disciplines is listed below, followed by the checklists relevant to it.

- General laboratory: the general laboratory checklist covers aspects such as proficiency testing, quality improvement, quality control, specimen collection and handling, laboratory computer services, personnel, physical facility, procedure manual and laboratory safety.
- Haematology and coagulation: blood and body fluid cell counts and differentials, coagulation tests, examination of bone marrow aspirate smear, and abnormal haemoglobin detection.
- Automated/general chemistry: common chemistry tests typically performed on automated instruments, including blood gas and oximetry.
- Urinalysis and clinical microscopy: automated and semi-automated urinalysis, dipsticks and dipstick readers, morphology systems, microscopic urinalysis, crystal and microscopic body fluid analysis and semen analysis.
- Toxicology: must be used for all screening and/or confirmatory testing for drugs of abuse and legal alcohols, regardless of methodology.
- Special chemistry: flame photometers, atomic absorption, spectrophotometers, immunoassays, electrophoresis, prenatal screening, alpha-fetoprotein and non-toxicological chromatography. Therapeutic drug monitoring regardless of instrument or method are included under the special chemistry checklist. Biochemical genetics is also covered by the special chemistry checklist.
- Microbiology: bacteriology, mycobacteriology, mycology, parasitology and virology. Any DNA amplification testing, such as PCR or LCR, is inspected with the molecular pathology checklist.
- Transfusion medicine: blood and tissue storage, compatibility testing, transfusions, donor collection, component preparation and parentage testing. Laboratories limiting their immunohaematology testing to A, B, O, Rh and antibody screening are inspected with the diagnostic immunology checklist.
- Immunology and syphilis serology: serology techniques, fluorescent stains and direct antigen detection.
- Anatomic pathology: all surgical pathology, including frozen sections, histology/histopathology, autopsies and electron microscopy.
- Cytopathology: all cytopathology, cell suspensions, screening and pathologist evaluations.

- **Cytogenetics:** amniotic fluid analyses, bone marrow cultures, chorionic villus sampling, blood lymphocyte analyses, solid tumours and non-neoplastic tissue cultures. (Biochemical genetics is covered by the special chemistry checklist, see before).
 - **Histocompatibility:** all transplants tissue compatibility (HLA) studies, including type/cross match and antibody identification. If flow cytometry is used for cross-matching, the flow cytometry checklist must be used.
 - **Flow cytometry:** evaluates flow cytometry assays. Testing covered includes: DNA analysis, lymphocyte phenotyping, leukaemia/lymphoma immunophenotyping and flow cytometry cross-matching for HLA.
 - **Molecular pathology:** molecular techniques for oncology, genetics, HLA/histocompatibility, parentage, forensic identity, *in situ* testing and infectious disease testing using nucleic acid amplification such as polymerase chain reaction (PCR) and ligase chain reaction (LCR).
 - **Limited service laboratory:** multi-discipline laboratories performing a limited number of common tests (e.g., outpatient or 'Stat' laboratories). This checklist is not appropriate for single-discipline or specialized laboratories, which should use the appropriate discipline checklist(s).
 - **Blood gas laboratory:** used for stand-alone blood gas laboratories that are under a different director, supervisor, location and/or CLIA number (only laboratories in the USA will have this number). If blood gases are performed in the laboratory under the same CLIA number as the main laboratory, with the same laboratory director, they may be inspected with the automated chemistry checklist. If blood gas tests are performed in a different laboratory section with a different supervisor, they would be inspected with the blood gas checklist.
 - **Point-of-care testing (POCT):** done in a non-dedicated space (i.e. with portable instrumentation). Dedicated laboratories require either a limited service or additional discipline checklist. A separate checklist must be completed for each POCT location, when POCT records are not maintained in a central location.
- The checklist questions are periodically revised. Each of the questions is uniquely numbered, worded and a 'closed'-type question designed to produce either a 'yes' response (i.e. the laboratory is compliant), a 'no' response (the laboratory is not compliant), or an N/A response (the question does not apply in this testing situation).
- Checklist questions are ranked and may be any of three types:
- **Phase 0:** these questions are for informational use only, e.g. 'Are you performing anatomic pathology services?'
 - **Phase I:** non-compliance with these questions may not seriously affect the quality of patient care or significantly endanger the safety and welfare of laboratory personnel, e.g. 'Are technical personnel tested for visual colour discrimination?' It is recommended that any such deficiencies be corrected if possible.
 - **Phase II:** these questions cover major deficiencies that may have a serious effect on the quality of patient care or may affect the health and safety of hospital or laboratory personnel, e.g. 'Has the laboratory documented a system for determining the accuracy and reliability

of analytic results on patient samples for which no external proficiency testing programme (CAP Survey) is offered? Laboratories must provide documentation of corrective action for Phase II deficiencies. Failure to do so may result in denial or revocation of accreditation.

Accreditation fees

The deposit to initiate the application process is currently set at US\$ 500.00 which is used towards the first year's accreditation fees if the laboratory is successfully accredited. The amount of additional fees payable for checklist sections depends on the number of checklist sections used. For example, for 1-4 checklists, 5-8 checklists and 9 checklists, the annual fees are currently US\$ 950.00, US\$ 1580.00, and US\$ 1860.00 respectively.

Inspection team expenses such as airline tickets, hotel accommodation and meals are paid for by the CAP central office for laboratories within the US. Usually, overseas laboratories will be charged for inspectors' airfares, in addition to the annual fees.

It is important, within the context of the laboratory's overall budget, that the cost of participating in the proficiency testing be added to the overall cost of accreditation. The level of proficiency testing fees will depend on the particular programme the laboratory is participating in. Laboratories interested in the accreditation programme should also take into consideration the costs involved in getting the laboratory accredited, and the costs involved in any corrective actions recommended by the inspectors.

Granting/denial of accreditation

Accreditation is formally granted by the CLA to laboratories that:

- successfully meet the standards for laboratory accreditation set forth by the CAP;
- correct (and document the corrections of) all Phase-II deficiencies within the specified time frames;
- successfully participate in proficiency testing programs for all required analytes;
- participate in mid-cycle self-evaluation processes; and
- resolve all issues and questions to the satisfaction of CAP technical associates and regional commissioners.

Denial or revocation of accreditation is possible in the following circumstances:

- the laboratory does not respond to the deficiencies cited during the on-site inspection;
- the laboratory fails to correct and document Phase II deficiencies;
- the laboratory fails to meet the CAP standards for laboratory accreditation; or
- the laboratory does not participate in self-evaluation.

Denial or revocation requires a vote of the entire CLA or a vote of the executive committee of the CLA. The CLA or its executive committee is presented with the facts surrounding the inspection, after which a vote is taken. Denial is followed by a certified letter to the laboratory director, effective immediately, and reported to the appropriate oversight agencies.

The laboratory may appeal against the decision within 60 days of receipt of notice. Documentation of compliance with all standards must be submitted to the CLA. The director may be invited to present the information at a CLA meeting, if facts not previously reviewed are provided that may affect the decision. Should the CLA adhere

to its original decision to revoke or deny accreditation, the laboratory may appeal to the CAP's Board of Governors. Three members will review the documentation and, if the appeal is considered valid, will refer the final decision to the entire Board of Governors [4].

Conclusion

Due to the absence of a national laboratory-accreditation body in Saudi Arabia and the associated difficulties in seeking accreditation internationally, the number of accredited laboratories in this country remains low.

This article highlights the need for developing a national medical-laboratory accreditation body, with responsibility for quality control and quality assessment issues. This would eliminate the problems and difficulties encountered in joining an international accreditation organization, and has the potential to evolve into a powerful tool for improving the quality of medical services provided in this country. The accreditation programme offered by CAP, with its excellent worldwide reputation and comprehensive coverage for all quality is-

ssues related to the different disciplines in medical laboratories, would be an ideal model on which to base such a national programme.

Establishing a national accreditation programme is a difficult and costly task for any country. However, by combining all available resources, the task is feasible. A Joint Committee for the Accreditation of Health Care Organizations, similar to the one in the US, will need to be established for this task. The membership of the committee could possibly be drawn from the following: all Ministry of Health laboratories, represented by the General Directorate for Laboratories and Blood Banks, all Ministry of Defence laboratories, all other government and privately-run laboratories, universities, and the Saudi Arabian Standards Organization (SASO). SASO has an excellent laboratory accreditation programme for industrial laboratories. Including this organization on a Committee for the Accreditation of Health Care Organizations would provide valuable local expertise. The formation of such a committee would help facilitate the creation of a national accreditation programme.

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Basics of quality assurance for intermediate and peripheral laboratories, 2nd edition

Despite significant improvement in health laboratory services in countries of the Eastern Mediterranean Region of WHO in recent years, there is still a need to establish or improve quality assurance programmes, particularly at intermediate and peripheral levels. This second edition of the highly successful *Basics of quality assurance for intermediate and peripheral laboratories* has been revised to better meet the needs of laboratory specialists, technologists and technicians at the front line of quality assurance. Chapters on quality assurance during the pre-analytical phases, control of laboratory investigations, data handling and processing, laboratory management and organization, use and maintenance of laboratory equipment, safety precautions in the laboratory, and external quality assessment have been revised and updated, and are supplemented by a new chapter on comparability of results. It is expected that this much needed publication will be of interest to developing countries throughout the world.