Establishing an Anatomic Pathology Laboratory at Cleveland Clinic Abu Dhabi

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Context.—The Department of Anatomic Pathology is a division of the Pathology & Laboratory Medicine Institute at Cleveland Clinic Abu Dhabi. The hospital offers the same model of care as its US-based counterpart the Cleveland Clinic, established in 1921 in Cleveland, Ohio. Pathology services at Cleveland Clinic are internationally acclaimed: the endeavor for Cleveland Clinic Abu Dhabi was to create a parallel facility, with the same standards in a greenfield start-up environment.

Objective.—To narrate how we addressed challenges customary in any laboratory start-up and issues distinctive to our setting with the aim to provide a model for others involved in a similar undertaking.

Data Sources.—All information in this article is based on published literature obtained by search on internet-based search engines, Clinical and Laboratory Standards Institute, and the authors’ firsthand experience.

Conclusions.—Key considerations in establishing an anatomic pathology laboratory are careful planning and design, adherence to local and international regulatory standards, selection of equipment and supplies, appropriate staffing, development of a laboratory information system, and sound test validation. In addition to meeting our clinical needs, alliance with the US Cleveland Clinic had an integral role in establishing our laboratory and regional reputation.


Cleveland Clinic Abu Dhabi (CCAD) is a contemporary, 364-bed, state-of-the-art, tertiary/quaternary care hospital on Al Maryah Island, Abu Dhabi, the capital of the United Arab Emirates (UAE). CCAD was the result of an agreement between Mubadala Investment Company (Abu Dhabi, UAE), and US-based Cleveland Clinic (Cleveland, Ohio) signed in 2006.1 The hospital was the keystone in the Abu Dhabi government’s Economic Vision 2030 to develop a robust, world-class health care sector in the UAE. This pioneering, multispecialty hospital was inaugurated in 2015 to reduce the need for UAE residents and citizens to travel abroad for treatment.

CCAD’s ability to provide world-class care rests on a foundation of high-quality diagnostic services. Critical to CCAD’s mission, the Department of Anatomic Pathology (AP) of the Pathology & Laboratory Medicine Institute (PLMI) at CCAD was established to fulfill the diagnostic needs of a very surgery-intensive organization. For details of the scope of CCAD and its various institutes, including PLMI, the reader should refer to the article by Mirza et al1 in this special section. In this article, we describe our efforts in establishing an AP laboratory in a greenfield American hospital, 7000 miles away from its parent organization. We share the challenges we faced in the geographic, cultural, and organizational context; the processes we implemented; and the solutions we devised.

STRUCTURE AND SERVICES

The AP laboratory at CCAD was established in collaboration with the National Reference Laboratory (NRL, Abu Dhabi, UAE), a stand-alone clinical laboratory.2 Inaugurated in 2012, NRL is a Mubadala Investment Company subsidiary, created in partnership with Laboratory Corporation of America Holdings (Burlington, North Carolina). Considering that CCAD’s scope of services required a hospital-based AP laboratory, Mubadala decided to create a joint AP laboratory at CCAD for economies of scale and efficiency. The division of labor between the 2 laboratory teams for AP services was that the pathologists, equipment, and physical laboratory space was to be provided by CCAD, and the technologists, supplies, and laboratory information system (LIS) were to be contributed by NRL.

Because a laboratory should meet the clinical needs of the patient population it serves, our services setup required that we not only build capacity to handle routine high-volume...
testing but also to perform specialized tests. In a hospital setting, factors that may influence in-house testing, irrespective of test volume and costs, are a necessity to avoid delays in diagnosis that could have a negative effect on patient outcomes, extend lengths of stay, increase overall treatment costs, and decrease efficiency. Our plans for comprehensive AP clinical services included surgical pathology and cytology. We decided early on to rely on the US Cleveland Clinic for second opinions and molecular diagnostics. Hospital-based medical autopsies are not practiced in the UAE and were, therefore, out of the scope of our mandate.

**Surgical Pathology Services**

CCAD’s mandate included providing comprehensive surgical care in cardiothoracic, neurology and endocrinology, ophthalmology, gastrointestinal, urology, and dermatology specialties. As a nontrauma facility, the hospital did not need to offer services in orthopedics. In addition, pediatrics, obstetrics, and gynecology were out of the scope of our mandate, except for pelvic floor repair in the latter specialty. However, NRL had all possible surgical specimens referred to it from its client base. Considering subspecialization in clinical medicine would place highly varied demands on our AP laboratory, we had to ensure high levels of diagnostic expertise with similar levels of subspecialization. Although that goal is achievable in mature institutions with high volumes and correspondingly high numbers of staff, we realized that it was not practical, cost-effective, or sustainable to match that subspecialization in a smaller, newly established organization. With a team of 6 pathologists, we decided to offer subspecialty reporting in areas that constituted a higher proportion of our practice, which included gastrointestinal pathology, gynecologic pathology, and dermatopathology.

Some of our pathologists provided expertise in multiple subspecialties, so we could also offer hematopathology, bone and soft tissue pathology, urologic pathology, breast pathology, head and neck, and endocrine pathology. Neuropathology, eye pathology, obstetrics and perinatal pathology, and pulmonary pathology were slated for reporting by general pathologists in partnership with subspecialists at the US Cleveland Clinic. Noteworthy is that our pathologists were trained either in North America or the United Kingdom, and although education programs differed, fellowships in the United States are comparable to experience gained by working with a subspecialty interest in the United Kingdom.

We established a digital/e-pathology system with US Cleveland Clinic for second opinions and molecular testing.1–3 The key disciplines of architecture, facility engineering, industrial hygiene, and safety engineering need to be involved in designing laboratories and are comprehensively detailed by Mirza et al1 in this special section. In Abu Dhabi, it is mandatory for all laboratories to fulfill requirements of local, municipal, and federal building codes, as well as licensing requirements of the Health Authority of Abu Dhabi (HAAD).4–9

**Equipment Validation.**—Our planned test menu included routine hematoxylin-eosin stains for histology, Papanicolaou and Diff-Quick (Kwik-Diff Stain Kit, Thermo Scientific, Runcorn, United Kingdom) stains for cytology, 25 special stains, and 160 immunohistochemistry (IHC), immunofluorescence, and in situ hybridization stains. Ideally, test validation should be the responsibility of technologist(s) and pathologist(s) with a keen interest in the field because it requires immense dedication and lays the foundation for correct clinical diagnoses for the entire team. The College of American Pathologists (CAP) requires that all equipment be verified before use to ensure that it will function as intended.10 A policy that states how all equipment is to be verified is part of the CAP requirements. At CCAD, instruments and equipment were verified by performing accuracy, precision, and comparison studies or whichever was applicable. After verification, planned, preventive maintenance was set for each instrument.

Preanalytic variables, such as cold ischemia time, fixation, and sample and section thickness, needed to be addressed early on to be able to provide consistently reliable results. The only required guideline for recording cold ischemia time for a tissue sample is associated with breast tissue samples that require estrogen receptor/progesterone receptor/Her2 testing to take no longer than 1 hour or results could be invalid.11–13 It is not always easy to determine and identify which tissue samples will require testing beyond what is routine and need a specific and sensitive test (ie, IHC or molecular testing).13 At CCAD, the computerized physician order entry in the electronic health record (EHR; Epic Systems, Inc, Madison, Wisconsin) for all specimen types includes the time a pathology sample is removed from the patient and the time before it is transferred to formalin.

Tissue processing programs also require validation. We ran test slides composed of several types of tissue, especially ones that we anticipated would have high-volume demand in our practice (eg, skin, gastrointestinal biopsies), and also tissues that included several types of nuclei (epithelial, muscle, lymphoid), various white blood cells (eosinophils, plasma cells), and several types of connective tissue and other tissue components to assess eosin staining (muscle, collagen, epithelial cells, mucin cells). Rapid protocols were verified for small biopsies, including transplants (renal, lung and cardiac). The checklist for recording verification testing and results listed all the solutions on the machine, the time spent in each container, the pH of appropriate solutions (eg, water, hematoxylin, eosin, acid rinse), the date and testing number, the name of the technologist performing the testing, and the name of the assessing pathologist. The
validation slides were evaluated by the pathologist as blind reviews. It is important that stains be assessed by established criteria as published by the UK National External Quality Assessment Scheme and/or a histotechnology reference book.14,15

**IHC Validation.**—Guidelines issued by the CAP mandate validation of all IHC tests before their use for clinical purposes.16 As a start-up, our laboratory did not have an internal source of archived tissue to perform validations or previously validated tests to compare with our validation results. We decided that the best action would be to source tissue from US Cleveland Clinic and compare our validation results with tests performed at the US Cleveland Clinic. To minimize preanalytic variability between our 2 laboratories, CCAD tissue handling protocols, including processing, were made identical to those of the US Cleveland Clinic. An optimized slide for each antibody, and validation material in the form of tissue microarrays and unstained whole
sections, were also provided by the US Cleveland Clinic. A decision was made to prioritize testing for antibodies that were most commonly used in an AP laboratory. In this case, the US Cleveland Clinic team generously shared their tissue and data. The project target timelines were to validate 25 antibodies per quarter, which, in hindsight, was an optimistic projection. All antibodies had to be optimized and the ideal protocol had to be determined by varying either the antibody dilution, and/or antigen retrieval. This took some time, even though the US Cleveland Clinic had shared their protocols with us. In addition to negative and positive tissue results, the validation plan for each antibody included weak expressers, which are essential to confirm antibody sensitivity. The plan also included a wide range of tissues for which use of an antibody may be clinically indicated. In addition to validation of formalin-fixed, paraffin-embedded tissues, we ran a small validation study for alcohol-fixed cytology samples, including cell blocks. The antibody panels selected for this study included common differential diagnoses encountered in cytopathology, such as the differential diagnosis of mesothelioma and adenocarcinoma, and common markers used for identifying a primary malignancy, such as caudal-related homeobox transcription factor 2 (CDX2) and thyroid transcription factor 1 (TTF1). In the initial phase of our laboratory operations, we issued a disclaimer when antibodies used had not been specifically validated for cytologic specimens. Furthermore, our validated antibodies did not work optimally in B5-fixed specimens, so we started to fix all of our bone/bone marrow specimens in 10% neutral-buffered formalin solution; if IHC results were negative, we still issued a disclaimer for decalcification.

For clinical testing, we built small tissue microarrays, which included positive, negative, and weak expressers as controls and which were cut on the same slide as the clinical test and efficiently monitored sensitivity and specificity. Feedback on each IHC test performed was provided to ensure optimal performance.

Specimen Arrival.—Although the use of a hospital pneumatic tube system for transporting surgical pathology specimens has been documented,17,18 we decided to have all pathology specimens hand delivered from the various hospital locations by nursing or perioperative staff to the main laboratory and not to use the pneumatic tube system. This decision was partly due to the team’s lack of experience with sending surgical pathology specimens through pneumatic tube systems and the lack of time to do proper validation studies for its effect on specimen integrity. Additionally, we wanted to avoid the risk of losing precious specimens in a new and unfamiliar system. Although batching of specimens is not recommended, delivery of smaller volumes can be coordinated with tissue processor runs to avoid unnecessarily frequent trips by transport staff to the laboratory. The number and timing of tissue processing runs was dictated by specimen volume and urgency. At CCAD, the tissue processors were run twice a day, a rapid run that starts at 0900 hours for specimens that arrived at the laboratory during the night from outside facilities and an overnight run for specimens that arrived during the day.

Specimen Handling.—Although receipt of specimens from the operating rooms (ORs) was originally meant to be in the adjacent OR laboratory (see below), our start-up volumes were not high enough to justify a dedicated pathology accessioner at that location; hence, we moved that activity to the main laboratory. Barcoded labels are used to prevent specimen identification errors when accessioning in the LIS. We employed the Lean methodology in setting up the main laboratory and used its processes to reduce waste of time and resources and to eliminate variability that may result in patient harm. We deployed 2 gross examination stations and placed worktops for cassette-label printers, weighing scales, and photography equipment, as well as an adjacent refrigerator for specimen storage. In calculating space for gross examination stations, sufficient room was allowed for computers and voice-recording equipment, which was attached to side arms to save floor space. The gross examination stations have to be adequately vented, and regular monitoring of formalin and xylene fumes is a safety requirement.10 Labeling of a predefined number of cassettes with barcodes for each specimen before gross examination standardized our practice. Cassettes are color coded for reporting priority and specimen source. To foster workflow efficiency, a cart for placing grossed specimens was also made available in the space. All wet specimens were retained according to CAP retention guidelines (a minimum of 2 weeks); empty biopsy containers are retained until the final report is issued to facilitate correction of any identification errors. All formalin is collected and neutralized before disposal.

To fulfill CAP requirements, templates for gross examinations of all specimens were standardized and built in Cerner PathNet (Cerner Corporation, Kansas City, Missouri). Those templates were used as Word documents (Microsoft, Redmond, Washington), with blanks to fill in measurements or customized for voice recognition (Dragon Medical Version 10; Nuance Communications, Inc, Burlington, Massachusetts). Goose-neck microphones were placed on the gross-examination stations, which have foot pedals so the pathologist’s or technologist’s hands are free to perform the gross examination. Pathologists’ use of voice-recognition frees up the technologists for other duties and also reduces transcription time. The CAP synoptic reports are also available in the LIS. Specimen tracking and workflow management were facilitated by the use of barcodes at every step of the workflow, including gross examination, sectioning, and slide submission.

Specimen Processing.—We obtained 2 Peloris II tissue processors (Leica Biosystems, Buffalo Grove, Illinois), which use xylene-free technology, and placed them adjacent to the embedding stations, microtomes, and water baths. The positive effect of the Ventana Symphony hematoxylin-eosin autostainer (Ventana Medical Systems, Inc, Tucson, Arizona) on histology workflow has been documented.39 The stain offers quality-controlled and continuously monitored baking, staining, and coverslipping function, producing a continuous output of trays of up to 20 slides. Waste from the stain drains through tubing, and disposal is the responsibility of Hospital Environmental Services; all chemical waste needs to be neutralized before disposal, in line with the Waste Management regulations.20 Manual hematoxylin-eosin staining can be performed in case of instrument failure. We also use automated special and IHC stained. The test menu for the special stain includes the most commonly used stains in the laboratory, and the few stains that cannot be automated are performed manually. Moreover, IHC is labor intensive, and automation significantly reduced the technical time involved and standardized the test performance. We ensured that all major pieces of equipment had alarm systems that notified users of potential malfunctions.
Supplies.—An inventory-management system for laboratory reagents and consumables should be in place to track purchasing, receiving, expiry dates, tracking, storage, use, and reordering. For our operations, a list of all reagents and consumables necessary to run laboratory operations was maintained by NRL. Reagents and equipment are stored according to manufacturer requirements of temperature and humidity. All reagents needed to be verified (ie, lot-to-lot verification, acceptance testing) before use in clinical testing. Timely replenishment and minimizing expiry are fundamental for management of supplies. For our AP laboratory, a quarterly inventory plan for the entire year was put in place, wherein all needed reagents and consumables for each quarter of the year are requested and ordered ahead of time. This plan is based on statistics on the regular usage of reagents and consumables. The data enables the laboratory to identify those with high-volume usage and those not performed as often and helps optimize the use of reagents.

Safety.—We implemented a chemical hygiene plan that detailed the safe storage, use, and disposal of all chemicals for the laboratory. All chemicals, in primary and secondary containers, are appropriately labeled according to Abu Dhabi Occupational Safety and Health guidelines and the staff are trained in safe handling of chemicals and how to respond should a spill or other accident occur. 

Appropriate personal protective equipment must be provided for all staff handling chemicals. Similarly, all cabinets and drawers require clear labeling regarding contents. Paraffin blocks and slides are stored near the laboratory; in particular, material from current and recent cases may be required for repeat tests, special tests, or IHC stains, or tumor boards and needs to be accessible by laboratory staff. Temperature and humidity are strictly monitored in storage areas to prevent deterioration of blocks. Entry to the long-term storage area was restricted, with withdrawal and return of slides and blocks monitored and documented.

Personnel.—Pathology departments must have appropriate staffing levels of pathologists, technologists, administrative, and information technology and clerical staff to meet the clinical, operational, and academic needs of an institution. Inadequate staffing of laboratories may compromise quality and throughput, whereas excess staff unnecessarily increases the cost of testing. There are few guidelines regarding how professional human-resource requirements for a pathology department should be calculated. Some guidelines for pathologists are based on case accessions, specimen numbers, and the population of the community served during the year. 

Per Canadian Association of Pathologists 2014 workload measurement guidelines and Royal College of Pathologists of United Kingdom, a pathology workload measurement system should also consider specimen complexity. Another proviso is that specimens deemed to be the same level of complexity by Current Procedural Terminology codes may have vastly differing cognitive and procedural complexity. Full-time equivalent staffing, based on specimen counts, also need to account for various types of leave (annual, sick, continuing medical education, among others) and management and academic responsibilities. In summary, there needs to be sufficient full-time equivalent employees to support activities, in addition to the number of staff members determined by calculation with specimen volumes.

Before the hospital opening, our volume projections were derived from the average of workloads of other government hospital laboratories in Abu Dhabi and were modified based on knowledge gained from prior work experience in the region. For the first year, those projections were 5000 surgical specimens, 5000 gynecologic cytology cases, and 1000 nongynecologic cytology cases. Those numbers were roughly expected to double in the second year and, then, to increase by 10% to 20% every year, in proportion to the hospital’s growth and the establishment of outreach programs. Job descriptions were drafted for all positions but were kept sufficiently general to allow for flexibility in the assignment of new tasks without needing revision. The constant change that is inevitable in a start-up should be discussed with all employees as part of orientation to clearly set expectations. One of the lessons quickly learned was that some candidates thought they were joining an established hospital like Cleveland Clinic in the United States, which has a history of 95 years of clinical excellence. It took them some time to realize that a start-up takes effort and time to evolve and mature. In our case, we also had a different cultural component because of our Middle East location.

CCAD is a physician-led medical facility and all pathology reports are provided by consultant pathologists licensed according to HAAD standards. The professional team consisted of 6 consultant pathologists inclusive of the chair of anatomic pathology, who led the pathology team. Initially, the pathologists were only involved in direct clinical care activities, mainly pathology reporting and consultations. Later, they also became engaged in multidisciplinary meetings and tumor boards. In addition to direct clinical care, we allocated the pathologists’ time for supporting activities, such as auditing, teaching, appraising, researching, clinical governance, and professional development.

Workforce calculations for technologists were performed by using the total number of tissue blocks processed per year in a medium-sized laboratory, and for cytotechnologists, the calculation was made on the total number of cytology accessions. We employed 5 histotechnologists inclusive of the AP supervisor and an IHC supervisor, and 3 cytotechnologists. All medical technologists have to be licensed by HAAD, which requires a relevant degree and at least 2 years of hospital laboratory experience. Accreditation requirements of the CAP necessitate technologists who perform high-complexity tasks (specifically, gross examinations) to be in compliance with Clinical Laboratory Improvement Amendments of 1988 regulations detailed on the Centers for Disease Control and Prevention Web site. Technical backup is necessary to provide a seamless workflow, and all our histotechnologists were cross-trained to handle all aspects of the histology workflow from accessioning to case distribution; the only exception to that multiskill parameter was IHC, which was performed by at least 1 more technician in addition to the IHC supervisor. A pathologist’s assistant (PA), who would take on the responsibility of gross examination on large/complex surgical specimens, is invaluable in conserving a pathologist’s time. The PA position is not currently recognized by HAAD; therefore, we recruited a junior pathologist, licensed as a specialist by HAAD, to help with gross examination of specimens. Specimen accessioners and laboratory assistants do not require licensing in Abu Dhabi.

Pathologist Offices.—The original laboratory design included pathologist offices next to the main laboratory to increase efficiency. Because of shortage of space for technical leads, the pathologists moved to the eighth floor.
of the hospital, which initially led to delays in slide delivery. However, we identified a short and designated route for the staff to reduce time spent in traveling between the laboratory and offices.

Pathologists were provided with high-quality microscopes, cameras with computers and monitors, simple polarizers, and micrometers in their offices. Immunofluorescence attachments and filters are necessary for renal biopsies and some skin and eye biopsies and, although optimally performed in a dedicated darkroom, can also be performed in offices with adjustable lighting.

We considered it important and feasible to have all pathologists on one floor to facilitate quick review of cases and seamless communication. We also set up a multiheaded microscope room adjacent to the pathologist offices, which is used for double reporting, sharing interesting cases, and teaching opportunities. We found that room to be instrumental in bringing the team together to foster professional exchange.

**OR Laboratory for Intraoperative Consultation**

We planned to have the OR laboratory on the same floor as the hospital ORs; the physical proximity was to enable a rapid turnaround time (20 minutes) for intraoperative consultations and to monitor that time as a key performance indicator. To ensure equipment backup in case of instrument failure and to facilitate simultaneous, multiple frozen sections, we placed 2 gross examination stations and 2 cryostats in the OR laboratory. The cryostat temperatures are kept between ~20°C and ~25°C and monitored daily; care was taken to avoid placement under an air vent which could have led to problems with maintaining temperature and frost accumulation. Worktops for manual staining were situated next to the cryostats. We also placed a camera for gross photography of specimens. Personal protective equipment was easily accessible for all staff involved in the frozen sections.

There is a separate reading room for pathologists with a double-headed microscope, a camera, and monitor screen. Although the gross examination station and the microscope both had cameras, we initially struggled with relaying those images to the surgeons in different ORs. Finally, we decided to share both the gross and microscopic images of specimens in real time between ORs and the OR laboratory with the screen-sharing feature of Skype (Skype Technologies, Palo Alto, California). Communication with hospital staff is by use of telephones and Vocera Communication (San Jose, California) devices. To facilitate communication, a list of telephone numbers of ORs and relevant pathology staff are placed near all telephones in the OR laboratory and in the pathologists’ reading room.

**Mohs Laboratory**

Although the reported incidence of skin cancer in the UAE is low,27 concerns about an increase in skin cancer incidence across UAE have been raised.28 Mohs micrographic surgery offers a high cure rate for skin cancer by microscopic examination of 100% of surgical margins at the time of surgery. We planned to offer that service in collaboration with the Mohs surgeon and positioned the Mohs laboratory close to the dermatology office to allow for a quiet space, especially for dissecting large specimens and to facilitate voice recognition for dictation. Sound seclusion in the gross examination area is hampered to some extent by background noise in an open laboratory. The quality of grossing stations and the fact that we placed 2 exhaust fans to extract fumes out of the laboratory allowed for the absence of a formalin odor in the area. Monitoring for formalin exposure is performed annually and is repeated any time there are

we divided the laboratory into a technical area with workbenches and a microscope viewing area; that proximity facilitates feedback regarding frozen sections between the Mohs surgeon and the laboratory technologist. A computer to enter a Mohs diagnosis in the patient’s EHR was made available in the laboratory. The designed workflow was that the specimens would arrive in the laboratory from the adjacent surgical room and be placed on an open countertop near the cryostat. We installed 2 cryostats in the laboratory; the second one was to be used as a backup if the main cryostat malfunctioned. An automated hematoxylin–eosin stainer was used and was preferable to manual staining, which we organized as a backup. We ensured adequate chemically resistant countertop space was available for staining. A second microscope near the cryostat and staining area was placed for preview of the slides by the Mohs technician. A fume hood with a back draft was made available to fit under overhead cabinets. The presence of a fan-powered exhaust vent that vents directly to the outdoors helped to decrease any chemical odors generated in the laboratory.

CCAD is somewhat unusual in that, although Mohs diagnoses are made by a dermatologist, the responsibility of technical support and management of the Mohs laboratory was assumed by PLMI. That was deemed necessary for licensing by the local regulator because all laboratories in Abu Dhabi need to be under the supervision of a laboratory director.7 Although the CAP requirement is that Mohs diagnosis should be made by a dermatologist, a Mohs surgeon, or a pathologist, there are no guidelines issued by international pathology accreditation bodies regarding frozen-to-paraffin correlations and the storage of Mohs section slides. We performed a documented correlation for all diagnostic biopsies and every fifth Mohs case. Although that added to overall cost of a case, we felt it was a necessary part of our quality assurance program. The dermatologist has the option to consult a pathologist should difficulties in interpretation of frozen sections arise. A slide storage system was created, and the slides are archived for a minimum of 10 years.30

**Challenges and Opportunities**

Long-term planning was largely driven by technologic developments, cost considerations, and anticipated changes in the scope of services, staffing, test methods, and equipment. Our vision included accreditation by United States and internationally recognized bodies and, therefore, conformance with CAP checklists.10 The International Organization for Standardization (ISO) guidelines (ISO 15189:2012),31 and standards from the Clinical and Laboratory Standards Institute (CLSI, Wayne, Pennsylvania) were followed from the outset to ensure high-quality service. Although our gross examination stations are in an open laboratory and allow visual management, we realized after becoming operational that it was best to have a separate room for gross examination to allow for a quiet space, especially for dissecting large specimens and to facilitate voice recognition for dictation. Sound seclusion in the gross examination area is hampered to some extent by background noise in an open laboratory. The quality of grossing stations and the fact that we placed 2 exhaust fans to extract fumes out of the laboratory allowed for the absence of a formalin odor in the area. Monitoring for formalin exposure is performed annually and is repeated any time there are
conditions that may be associated with personnel exposure to formalin or xylene.

At the time of the hospital’s opening, we planned for an instrument backup for all steps in routine tissue processing and staining, except for the IHC stainer. That gap in our planning created difficulties when the workload caught up with the run capacity of the IHC stainer, and we recently had to add another instrument. The second stainer also helped us to better manage the IHC technologist’s valuable time, ensuring that he or she did not have to remain after regular working hours to initiate the last run. Another important consideration in instrument selection was the availability of instrument maintenance from the vendor. We strived to minimize the number of vendors to ease the management of the maintenance contracts.

Setting up inventory management must take into account shipping delivery times and customs regulations. Shortage is the most commonly encountered problem when it comes to supply management. Despite an inventory plan, it is inevitable that problems in supply management will be encountered that are beyond the control of the laboratory. Examples of supply problems include unavailable stock from vendors and reagents with short shelf life. In addition, irregular inventory upkeep in the laboratory can lead to shortages, which could be a result of staffing shortages or task performance by different individuals in the absence of standardized work. An automated inventory management system was the ideal way to ensure adequate reagent supply and to enable a much more streamlined method of controlling inventory.

Because validation of our entire IHC test menu was planned for 2 years, we set up digital IHC in collaboration with the US Cleveland Clinic to fill in gaps for tests that were not available in house at any point. Our pathologists successfully participated in a validation study consisting of a mix of cases that included strong positive, weak positive, and negative results. Cases were first read on virtual slides, and after 2 months were compared with those read on corresponding glass slides. 32,33 Unstained sections were scanned by digital pathology, and a link was emailed performed either the same or next day. The stained slides arrived there in 2 days. Upon receipt, the stains were shipped for IHC staining to the US Cleveland Clinic, which is a very effective way of 

Transcription of pathology reports is performed by pathologists using either quick-text templates in Cerner PathNet (Cerner Corporation) or voice recognition. Because workloads have increased, the need for medical transcriptionists has become increasingly necessary to use the transcriptionist’s time efficiently. In the interim, pathologists receive regular feedback from a monthly audit to minimize variations in reporting formats. We began to offer Mohs procedures on one assigned day each week. Because the volumes at start-up were not high, the quality assurance activity did not take up significant pathologist time. However, as volumes increase, pathologist involvement may correspondingly increase, and both pathologist availability and the costs involved may require changes to quality management in that area. These issues are somewhat unaddressed by accreditation bodies, and it is anticipated more-defined guidelines will surface in the future.

**CYTOPATHOLOGY SERVICES**

We provide both gynecologic and nongynecologic cytopathology services, including rapid on-site evaluation (ROSE) for adequacy of fine-needle aspirations (FNAs) in clinics. We use ThinPrep (Hologic Inc., Marlborough, Massachusetts) for both gynecologic and nongynecologic cytology. Cytology staining and coverslipping are conducted under fume hoods.

**ROSE Evaluation for Cytology**

ROSE for adequacy of FNA smears and biopsy touch imprints improves sampling yield and is especially helpful for expensive, image-guided FNAs. The benefits of reducing repeat procedures, needle passes, and consequent complications need to be balanced against the increased costs incurred from use of cytology personnel and length of procedure.34

At start-up, the team employed one cytotechnologist, and we had to earmark 4 locations for FNAs—the thyroid clinic, the ultrasound room in imaging department, the bronchoscopy suites (endobronchial ultrasound-guided FNAs), and the endoscopy rooms (endoscopic ultrasound FNAs). Given the difficulty in moving microscopes and staining racks between multiple locations and the risk of reagent spillage and microscope damage, we placed a permanent microscope and cytology supplies at the service locations for optimal and smooth operations. We use a rapid Papanicolaou or Diff-Quik (Thermo Scientific) for staining slides, depending on pathologist preferences. It is important that fumes from chemicals and reagents are vented into a minifume hood. The aspiration is performed by a clinician, the slides are prepared by a cytotechnologist, and adequacy assessment performed by a cytopathologist. ROSE service was scheduled for different clinical services on designated days of the week and is activated by the requesting physician sending an invitation through a cytology group email. The cytopathologist is called on site by the cytotechnologist when the slides are ready.

With our clinical colleagues, we collaboratively defined the number of passes, number of smears, and workflow for each organ site, along with the use of needle rinses in CytoLyt Solution (Hologic Inc.) and preparation of one ThinPrep test (Hologic Inc.), which is a very effective way of reducing the number of slides generated by each procedure and, thereby, the time spent for screening and diagnosis. We
have learned that it is important to remind physicians to wait for results of 1 to 2 passes because repeat sampling defeats the purpose of on-site assessment and increases patient morbidity.\(^{35}\) Additionally, triage for microbiologic tests, flow cytometry, and molecular testing on site guarantees adequate material for all studies in most cases.

**Challenges and Opportunities**

One of the nonconformances raised during our ISO 5189 assessment was that all cytology preparations in the main laboratory should be conducted in a biosafety cabinet (Biological Safety Level-2) rather than a fume hood, which we were using at the time. We also sometimes use a rapid Papanicolaou stain in ROSE clinics and have lately realized that a minifumehood is essential because of the xylene content. We are in the process of making these changes.

ROSE is known to have the greatest impact in centers with a high rate of unsatisfactory specimens; we have not tested this aspect of our service because this service at CCAD was established at the request of ordering physicians. Additional advantages are improved physician and patient satisfaction, with a positive effect on the reputation of the laboratory and the organization. We have found it to be an efficiently run and well-reputed service at CCAD.

**PATHOLOGY LIS**

**Clinical Perspectives**

The LIS controls much of the functionality and workflow of an AP laboratory from test ordering and specimen processing to final reporting of results. Consequently, a laboratory’s capability to deliver services is dependent on its LIS, and pathologists should be actively involved in the selection and design of the system and its functionality. An important consideration when selecting an LIS is whether to obtain one from the same software vendor that supplies the EHR or to choose software from an independent vendor. In theory, selecting an LIS from an independent vendor allows the laboratory to obtain a product that is optimal; however, that approach entails considerable effort and expense associated with managing the interfaces. In contrast, data flow between an EHR and LIS from the same vendor is usually seamless, and that is often a simpler and safer approach. In the case of CCAD, the choice of LIS for AP was driven by 2 main factors. First, the Epic system (Epic Systems, Inc., Madison, Wisconsin) is the EHR, and at the time of LIS selection, the Epic LIS was still under development. Second, the collaboration with NRL provided an external client base, which the laboratory at CCAD also serves. NRL has implemented Cerner Millennium for an external client base, which the laboratory at CCAD also serves. NRL has implemented Cerner Millennium for clinical pathology and had clients interfaced to that system. Furthermore, Cerner is well established in the region, with a comprehensive and were reviewed by subspecialty clinicians. In the ambulatory clinics, generic admission, discharge, and transfer labels were deployed and we had to accept the limitation of specimen source being handwritten on the label. That is apparently a gap that cannot be resolved unless the EHR and LIS are provided by the same vendor. Some specimen collection vials are small, such as CytoLyt, and cannot accommodate a large pathology label. That is apparently a gap that cannot be resolved unless the EHR and LIS are provided by the same vendor.

Hardware and software requirements, environmental conditions and safeguards for maintaining optimal opera-

![Figure 3. Integration of Epic electronic medical record system (Epic Systems, Inc, Madison, Wisconsin) and Millennium PathNet system (Cerner Corporation, Kansas City, MO) as anatomic pathology (AP) laboratory information system (LIS). Abbreviation: ESB, Enterprise Service Bus.](image-url)

- **Electronic Medical Record (Epic)**
  - Anatomic Pathology Orders
  - Result Reporting
  - Charges for AP Test
- **Interface Engine (ESB)**
- **AP LIS System (Cerner)**
  - Anatomic Pathology Orders
  - Result Reporting
  - Charges for AP Test

- **System Diagram**

- **Figure 3.** Integration of Epic electronic medical record system (Epic Systems, Inc, Madison, Wisconsin) and Millennium PathNet system (Cerner Corporation, Kansas City, MO) as anatomic pathology (AP) laboratory information system (LIS). Abbreviation: ESB, Enterprise Service Bus.
fields in each order, and some examples are shown in the Table.

The AP LIS generates reports with different statuses, including final, preliminary, addendum, and amended (revised) reports. A preliminary intraoperative consultation report is issued at CCAD for documentation and facilitates quality-assurance functions of frozen-to-paraffin correlation. Gynecologic and nongynecologic cytology to histology correlations are also supported by the LIS. All reports linked to a laboratory accession number are maintained in the system and appear in chronologic order; for example, all preliminary reports are followed by final reports. Addendums and amended reports follow a final report; the reason for an amendment or a critical notification is documented in the reports. The option of correcting an issued report also exists; these corrections are issued for minor transcription errors that do not affect case management, and the reason for correction is included in the report. The LIS also supports data analysis for audits, clinical risk management, disease surveillance, and epidemiology, such as cancer registration, screening programs, communicable disease reporting, and external quality-assessment data management.

Challenges and Opportunities

Since activation, significant features have been added to our LIS. The prefix anatomic pathology was added to the Epic specimen label, which supports sorting at central laboratory reception and effectively resolved the problem of both lost specimens and delays in tracking pathology specimens that were misdirected to clinical pathology. We also considered the option of different color labels to facilitate sorting. Synoptic reports, although available in the Cerner LIS, need to be updated within a specified amount of time if there are any changes in the CAP protocols, and that should be specified in the terms of vendor contracts. Additionally, we recommend that laboratories specify key performance indicators for the information technology system, some of which may include minimum down time, time taken to complete service requests, and response to user feedback. On-going work is also being done to highlight critical AP results in the Epic EHR.

REFERENCE LABORATORIES

A reference laboratory may be used to provide esoteric tests or as a backup provider for services. Criteria necessary in selecting a reference laboratory include the maintenance of formal licensure and accreditation status, a well-defined and operational quality-management system that is regularly evaluated, accuracy of results, quick turnaround times, reputation, and the availability of pathologists for consultation. The ultimate responsibility for selection of a reference laboratory lies with the laboratory medical director of the referral laboratory.

Specimen transport and mechanisms for reporting results must be clearly defined in the contract or service level agreement; care should be taken to determine whether transport time is included in the turnaround time. The process of selection and a record of performance by reference laboratories must be maintained and may include performance in proficiency testing, turnaround times, amended report rates, and the quality of reports.

Adherence to specimen submission guidelines of the reference laboratory is essential because any deviation may affect the final result. The reporting or release of reference laboratory results to the requestor is the responsibility of the referring laboratory. The report of the referring laboratory must clarify which part of the report is based on the reference laboratory report, which must be incorporated so as not to alter the clinical meaning. At CCAD, we prefer to make a copy of the reference laboratory report available to the requesting physician by uploading it into the patient’s EHR, so that no error is possible in interpretation.

Challenges and Opportunities

As a start-up, our priorities in selection of a reference laboratory were not limited to filling our current clinical gaps but also with promoting in-house test development and facilitating our long-term vision of becoming an academic and research institution. Those objectives were well met by the choice of the US Cleveland Clinic as the reference laboratory for anatomic pathology. Cleveland Clinic has more than 50 subspecialty pathologists who comprehensively meet all our clinical requirements, notably in neuropathology, ocular pathology, transplantation pathology, renal pathology, and electron microscopy; difficult cases in all other subspecialties are referred to the US Cleveland Clinic. We found ease and readiness of pathologist availability for consultation without the need for going through a contact/client response center. Our IHC validation continues to be generously supported by the US Cleveland Clinic, both in the form of materials (tissue microarrays, whole slides, and optimized slides for comparison) and in knowledge exchange between pathologists and technologists in matters such as the selection of antibody clones for IHC and troubleshooting. Our digital pathology program was established with considerable help from US Cleveland Clinic and is now well regarded for its remarkably quick turnaround time of less than 3 days for subspecialty overseas consultations and 2 days for IHC requests. That collaboration and support has made a tremendous impact on patient care at CCAD.
QUALITY MANAGEMENT SYSTEM

A comprehensive quality-management system should address the preanalytic, analytic, and postanalytic cycles of a test.\textsuperscript{39,40} Details of the 12 quality-system essentials of CLSI, which form the building blocks of our system, are beyond the scope of this article.\textsuperscript{41} Based on the descriptions above, there were more than 120 documents related to the AP quality management system managed electronically in PolicyTech (Navex Global, Lake Oswego, Oregon), the document control system for PLMI at CCAD. The aim was to cover every aspect of the workflow in the laboratory, meet the requirements of all accreditation bodies, and make a soft copy available to all laboratory personnel. The title of each document, its target audience, its author(s) and approver(s), and the date of approval and revisions are clearly identified in the document header.\textsuperscript{42} Because we are a joint laboratory, our document approval includes NRL signatories to ensure compliance from all staff. Documents written at the time of operational start-up invariably needed some modifications as workflows matured and points of impracticality surfaced. New accreditation and regulatory requirements can also drive revisions during annual reviews. To prevent errors arising from the availability of an older version we decided not to have hard copies of any documents in the laboratory. A backup of all the documents in PolicyTech is kept on a local computer and automatically updated weekly to ensure access to essential documents during downtime. Document control is always a work in progress. Old versions are archived in the system and accessible only to members of the laboratory quality team with administrative access.

Regulatory Compliance

Clinical laboratories in Abu Dhabi need to be compliant with the Clinical Laboratory Standards (2013),\textsuperscript{39} issued by HAAD, which also licenses and monitors the performance of medical laboratory facilities. As of January 2017, ISO 15189:2012 accreditation has also become mandatory for all laboratories in the UAE and conformance with their requirements is also essential.\textsuperscript{31} All other accreditations are optional. Within the short span of 2 years after opening, PLMI achieved the standards requisite for licensing and accreditation by HAAD and ISO 15189:2012, respectively, and was additionally accredited by the CAP.\textsuperscript{42}

Challenges and Opportunities

A challenge in applying ISO 15189:2012 terminology in AP was that most of our reports lacked numerical results and were subject to interpretation; moreover, the ISO accredits an individual test and, unlike CAP accreditation, technical and professional components of the AP cannot be accredited separately.\textsuperscript{33} That was a major issue for us because our technical component was supported by the NRL. To resolve that, we had to submit a separate application for the joint CCAD-NRL AP laboratory with ISO. Our licensing and accreditation journey is detailed in the article in this special section by AbdelWareth et al.\textsuperscript{42}

CONCLUSIONS

We have been on a journey of learning in our efforts to establish an AP laboratory at CCAD, which required a comprehensive scope of activity to meet the needs of the hospital and work referred by external clients. Because of the tremendous team effort between CCAD and NRL, as well as the unwavering support provided by the US Cleveland Clinic, we have been able to achieve the objectives of providing timely, efficient, and quality care to our patients. Our commitment to local and international regulatory and accreditation standards and our quality management program underpin our viability and success. Our richest resources are the caregivers who made all this happen, who accepted every challenge with enthusiasm, pride, and resilience in an effort to provide world-class pathology services to the people of the UAE and the wider region. Vital to sustaining this success is the ability to learn from the past and to strategically plan for the anticipated future.


