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HINDUJA HOSPITAL

LAB COMMUNIQUE

Keeping pace with technlogy...

QC and Good Lab Practices

CONTENT

Editor:
Dr. Anita Bhaduri, MD, Surgical Pathologist

For Editorial Enquiries write to us at:
info@hindujahospital.com

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Marketing Department
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Veer Savarkar Marg, Mahim,
Mumbai - 400016, (INDIA).
Tel.: +91-22-2445 1515/ 2444 2222/ 2444 9199
Fax: +91-22-24449151
Website: www.hindujahospital.com

EDITORIAL

Happy reading!

Dr. Anita Bhaduri

Infection control - its time to act

Dr. Anjali Shetty,
MRCP, FRCP – Pathology
Consultant Microbiology

> It is important to use single use vials for injections as the use of multidose vials can lead to contamination of the drug giving rise to infections.

Most public and private hospitals today have their house in order with regards to infection control: an active infection control committee, a manual full of policies and a packed schedule of teaching sessions and surveillance of hospital acquired infections. Accreditation by the National board of hospitals has helped in raising the profile of infection control. Its time we looked at implementing the principles of infection control in private clinics and nursing homes which do not come under the purview of accreditation boards thus leading to varied standards.

Procedures done at private clinics include intramuscular injections, administering intravenous fluids and performing surgical dressings. The most important thing to remember prior to embarking on any procedure is hand hygiene. This would involve rubbing ones hands with alcohol for 30seconds to one minute. It is important to wait till the alcohol evaporates. If hands are visibly soiled then handwashing with soap and water would be required.

It is important to use single use vials for injections as the use of multidose vials can lead to contamination of the drug giving rise to infections. Abscesses due to Staphylococcus aureus, non-tuberculous mycobacteria and necrotising soft-tissue infections due to fungi such as mucorales, have all been reported due to poor infection control whilst administering intramuscular injections.

Intravenous fluids must be procured from reliable sources and they must be checked for turbidity, broken seals etc prior to administration. In northern India an outbreak of aspergillus endophthalmitis was traced back to fungal contamination of intraveous dextrose solution.

Needles, syringes, scalpel blades should all be single use. Gauze should be sterile. Forceps used for suturing etc should be sterilized appropriately. The general practice is to boil the instruments in water and leave them in water, till the instruments are needed. This luke warm water is a good breeding ground for microbes and can easily lead to recontamination of instruments. Perhaps it is better for all surgical instruments from private clinics and nursing homes to be sent to a central sterile services department so that they are effectively sterilized. This department could also provide clinics with sterile gauze and cotton.

Insertion of devices such as urinary catheters should only be done if there is a clear indication such as urinary retention rather than for incontinence. Condom catheters and intermittent self catheterization should be used as options instead. Early removal of urinary catheters is essential to reduce the risk of infection. It is important to maintain

> It is important to use single use vials for injections as the use of multidose vials can lead to contamination of the drug giving rise to infections.

a closed system as any break in the system could lead to introduction of bacteria. Patients should be advised that the collection bag should never be placed at a higher level than the catheter tubing as this could lead to back flow of urine from the bag to the bladder leading to infection. Care should be taken while emptying the catheter bag, hand hygiene is of utmost importance. There is no evidence to suggest that replacing functioning urinary catheters at regular intervals reduces the risk of infection.

In some nursing homes central line insertion is carried out. This procedure needs to be performed under strict aseptic precautions or else patients can have catheter related blood stream infections. Whilst inserting a central line one must take the following precautions - mask, cap, sterile gloves, gown, >0.5% chlorhexidine and alcohol for skin preparation and use of sterile drape that completely covers the patient from head to toe. Gauze dressing would need to be changed at least every 48 hours or when soiled. Transparent dressings would need to be changed at least once a week or when soiled. There is no need to routinely change central catheters.

With increasing awareness among the general public it is time infection control is given its rightful place in patient management.

Suggested reading

1.Guidelines for the prevention of intravascular catheter related infection. Clin Infect Dis 2011; 52: e1-e32

2.Diagnosis, Prevention and treatment of catheter associated urinary tract infection in adults 2009-International Clinical Practice guidelines from Infectious Diseases Society of America. Clin Infect Dis 2010; 50: 625-663

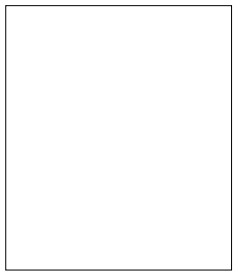
Doctor's Profile

Dr. Anjali Shetty,
MRCP, FRCP – Pathology Consultant Microbiology

Professional Experience
Dr. Anjali Shetty has more than 11 years experience both abroad and in India. Her special areas of interest are clinical bacteriology and infection control.
Research & Publications
Dr. Shetty has numerous publications to her credit in both international and national journals and one of her recent publications includes "Outbreak of Listeria Monocytogenes in an Oncology Unit Associated with Sandwiches Consumed in Hospital". The same was in association with Davies E, Mclaughlin J, Grant C, Ribeiro CD and was published in Journal of Hospital Infection.
Awards and Achievements
She has been awarded the Travel Bursary Award by the Hospital Infection Society for lecture in South Africa on Infection Control and for the best oral presentation at BIS in May 2005 for "A Case of Colonic Stricture in a Neonate" along with Barnes RA.

dr_ashetty@hindujahospital.com || Ph: 022-24451515 Extn

Quality control guidelines and policies for a Flow cytometry laboratory



Dr Kunal Sehgal,
Associate Consultant, Hematology,
PD Hinduja National Hospital
M.D. Pathology
(PGIMER Chandigarh)
UICC Fellow Flowcytometry and Hematopathology
(John Hopkins Hospital, USA)
Ex-Resident and Fellow,
Hematopathology Laboratory
(Tata Memorial Hospital, Mumbai)

Accreditation and Quality are the buzzwords in the lab world today. Accreditation requires that every laboratory follows a set of standard guidelines and policies. Clinical Flow Cytometry laboratories offer a wide range of services and there has been a huge expansion in this field over the last five years in India. This article aims to provide a framework for the guidelines and policies to be followed for quality and accreditation in any clinical flow cytometry laboratory. Present article is aimed at the flow cytometry laboratory technologists and doctors to help them initiate and work towards getting laboratory accreditation. It also incorporates measures of how individual policy compliance may be assessed by assessors of an accreditation program.

Quality manuals and Policies

Any flowcytometry laboratory participating in the accreditation program should have a well written QM manual which covers the preanalytical, analytical and post analytical procedures performed in the laboratory. This should cover all aspects from patient identification and preparation to specimen collection and processing; and to accurate, timely result reporting. Each lab should define its procedures and methods for patient identification, patient preparation, specimen collection and labeling, specimen preservation, and conditions for transportation, and storage before testing. Blood and Bone marrow samples may be stored at room temperature overnight. Fluid samples and aspirates and suspected cases of Burkitts lymphoma may be refrigerated at 2-8°C. Each laboratory should have a set of well defined sample rejection criteria. In case of unacceptable samples, the same should be informed to the treating physician and recorded. All bone marrow samples are precious and the same is to be kept in mind before completely rejecting a specimen.

Reagents and basic equipments

All labs should have a documented reagents purchase policy, storage policy, labeling policy and a policy for confirming and documenting the reactivity of the reagents used in the lab. This may be achieved by direct analysis with reference materials, verification testing of old vs. new reagents, and checking against routine controls. All reagents should be stored as per manufacturer's guidelines. The laboratory must assign an expiration date to any reagents that do not have a manufacturer-provided expiration date. The assigned expiration date should be based on known stability, frequency of use, storage conditions, and risk of deterioration.

Thermometers should be present on all temperature-controlled instruments and environments and checked daily. Thermometers or automated sensing devices should be recalibrated or recertified on a

regular basis as per manufacturer guidelines. Automatic pipettes used for quantitative dispensing are checked for accuracy and reproducibility at least annually, with documentation of calibration results.

Quality Control

The frequency of running QC material depends on the type of test being performed. A QC sample has to be run on each day of analysis for lymphocyte subset and CD34+ stem cell measurements, regardless of whether one- or two-platform methods are used and at least monthly for leukemia/lymphoma immunophenotyping. For measurements of CD4+ lymphocyte and CD34+ stem cell concentrations two levels of commercial controls are ideal. It is important to have a low level control for both CD34+ and lymphocyte subset assays, as clinical decisions are commonly made at low counts. Internal positive controls can be used only for leukemia/lymphoma samples. Such internal control cells are the residual normal cells in the patient's sample.

Each lab should have a documented policy defining the range of quality control material and various levels of corrective actions to be taken when unacceptable QC results are obtained.

INSTRUMENTS AND EQUIPMENT

All instruments and equipment should be properly installed, operated, maintained, serviced, and monitored to ensure that malfunctions of these instruments and equipment do not adversely affect the analytical results. The maintenance procedures should be followed as per manufacturer's guidelines. A maintenance log detailing the daily, weekly, monthly, semi-annual and annual maintenance procedures should be maintained. Any unscheduled maintenance procedures must be documented in the same log and this should be reviewed by the supervisor/consultant on a monthly basis. Instrument function checks are ideally done by commercially available quality control beads. These may be different for different instruments and should be selected based on the instrument and manufacturer guidelines. The following parameters are to be monitored : Laser Current and Laser Power, PMT Voltages, Fluorochrome Sensitivity, Laser Delay (when applicable on multi laser instruments), Window Extension (when applicable), Area Scaling Factors (when applicable on digital flow cytometers) and Fluidics.

Compensation Controls

Each lab needs to document the procedure of how the color compensation is going to be setup. This can be done manually or by automated methods. Compensation experiment can be done using cells or beads. However it is important to optimize the settings given by the beads with cells to be used in the actual experiment. The frequency of doing compensation settings is to be decided by the individual labs. However it is essential to reestablish compensation values after any hardware change, laser realignment, and change in filters, optics or any other such parameters which affect

instrument performance.It is essential to note that compensation settings are stable for a given set of PMT voltages. Any change of PMT voltages on a case to case basis will have an adverse affect on compensation values and should be avoided. Compensation values between different parameters should be documented and may be plotted on a LJ chart to evaluate instrument performance over a period of time.

Assay Procedures

Each lab should have a documented policy for evaluation of viability.

Leukemia/Lymphoma Immunophenotyping- Each lab should establish procedures to ensure that viable cells are analyzed. This does not mean that all specimens with low viability must be rejected. Finding an abnormal population in a specimen with poor viability may be valuable but the failure to find an abnormality should be interpreted with caution. If specimen viability is below the established laboratory minimum, test results may not be reliable and this should be noted in the test report. Routine viability testing may not be necessary. However, viability testing of specimens with a high risk of loss of viability, such as FNAC samples, stored fluid samples, disaggregated lymph node specimens, is required.

Lymphocyte subset enumeration- Routine viability testing is not necessary on specimens of whole blood that are analyzed within 24 hours of drawing.

CD34+enumeration- Viability testing is not necessary on peripheral blood or apheresis specimens that are stained and analyzed within 4 hours of drawing (harvesting).

Antibody Panels

The panel of monoclonal antibodies employed must be sufficiently comprehensive to address the clinical problem under consideration. Each lab should try and establish a comprehensive panel of markers which should cover all common differential diagnosis. The clinical picture and morphological findings are very useful in deciding on a particular panel of antibodies. For CD34+ stem cell enumeration appropriately conjugated Class II or Class III anti-CD34 monoclonal antibodies are used.

It is important to define the cell concentration to be used per assay tube for a given assay. This may be based as per the manufacturer guidelines or on existing clinical practices. A recommended cell concentration to be used for routine immunophenotyping is 0.1 -1 million (0.1 -1 x 106) cells per assay tube. It is important to note that as antibody staining is mainly volume dependent, the sample volume used in your assay should be constant. The cell number can be adjusted by spinning down the cells and re-suspending them in a desired volume. For fluids, aspirates and specimens with low counts, lower cell concentration may be used and restricted panels may be applied as per the clinical scenario.

Data Acquisition

Leukemia/Lymphoma Immunophenotyping- A minimum of 30000 events should be acquired.

More events may be acquired if there is marked degeneration of sample or when rare populations are being evaluated.

Lymphocyte subset enumeration- For Single platform measurements, manufacturer guidelines are to be followed.

CD34+enumeration- The maximum coefficient of variation for CD34+ cell counts should be 10%. To achieve this precision, a minimum of 100 CD34+ events should be counted, as recommended by the ISHAGE guidelines.

Gating Strategies

Each lab should have documented policies of appropriate gating strategies to be used for the different panels. CD45 vs. light scatter gating is a must while evaluating acute leukemias. For evaluation of lymphomas though CD19 and CD3 gating is ideal, CD 45 vs. light scatter or forward vs. side scatter gating may also be used. For leukemia and lymphoma immunophenotyping, the placement of quadrant markers should be based on unstained cells and internal negative and positive controls. Isotype controls may be used in place of unstained cell but their use is not essential.

ISHAGE protocol is ideal for CD34 stem cell enumeration. CD45/CD3 gating is essential for CD4 subset enumeration.

Flowcytometry Reporting

Atleast two unique patient identification indicators should be used in the report. These may include name, age, sex, laboratory number, sample number etc. The report should include the Clinical history in short, Specimen type, Instrument and Software used, Gating strategies and Cell preparation method.The final report should include descriptive information about the immunophenotype of the abnormal cells, if identified, and comments necessary to facilitate the interpretation.The details of the antibodies used can be given in a tabulated format along with the interpretation of positivity or negativity. Stress should be laid on interpreting the intensity of positivity and not on percentages. While interpreting the intensity of positivity as normal, bright or dim, the abnormal population should be evaluated against known normal leukocyte populations.The final impression should be clearly stated along with a differential diagnosis if required. Comments and suggestions regarding useful follow up test or other ancillary techniques should be added. The lab is recommended to follow the WHO 2008 guidelines for the classification of hematolymphoid neoplasms in the reporting of results.

Data Backup and Storage

All list mode files, experiments with analysed templates or pdf copies of the same should be backed up on a regular basis. All list mode files and final reports should be stored for a minimum period of 10 years.

Flow Cytometry Lab Personnel

The person in charge of technical operations in flow cytometry has education equivalent to that of a science graduate and at least a 3-6 months hands on experience in a

busy flowcytometry laboratory. The operating technician should attend CMEs and workshops for continual improvement.The signatory authority should be a MD/DNB/DM in the field of Pathology or Hematology. He/She should have Atleast a one year experience in a busy flowcytometry laboratory. Exposure to CME and workshops on a yearly basis is recommended.

Quality improvement program
Each lab should on a yearly basis set defined quality improvement goals. These should cover all aspects, from the pre to the post analytical parts of the assay. These quality improvement indicators may be the turn around time of the test, number of samples requiring complete repeat processing, number of clerical/technical errors etc.

Doctor's Profile

Quality assurance in a Biochemical Genetics Laboratory

Dr. Alpa J Dherai,
Ph.D
Consultant Biochemist

Biochemical genetics laboratory (BGL) is a stream of clinical chemistry specializing in diagnosis of inborn errors of metabolism(IEMs). IEMs are individually rare but collectively form a group of >500 disorders. The genetic defect in the metabolic pathway leads to deficiency or altered activity of an enzyme leading to an accumulation of substrate or absence of a product(Fig 1). The accumulation of these metabolites causes toxic effects. The clinical presentation is usually overlapping within IEMs and also in the non metabolic conditions such as infection and intoxication. The diagnosis of these disorders can be instigated at metabolite, enzyme or molecular level.

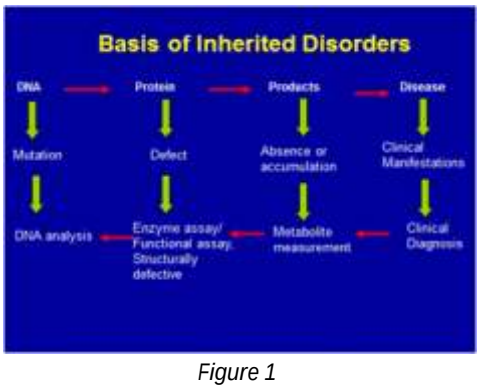


Figure 1
Basis of Inborn errors of metabolism

The functional areas of these laboratories include screening, diagnostic testing, monitoring of treatment, carrier testing and prenatal diagnosis. Each of this functional area has significant complexity and requires expertise and knowledge of variable phenotypes and metabolic pathways of these rare disorders. The establishment of these laboratories requires well-defined quality standards for pre analytical, analytical and post analytical variables thereby ensuring reliable testing services.

Pre analytical variables

Preanalytical variables like mislabeling of samples, appropriate sample, sample shipment etc remain common to all other clinical chemistry laboratories. The primary challenge for diagnosis of IEM isthe time of sample collection, instability of the enzymes and metabolites and thus appropriate transport condition. The samples range from whole blood and body fluids, filter paper blotted samples, tissue biopsies and prenatal samples like chorionic villi and amniotic fluid. Each of these have characteristic shipment requirements varying from room temperature for blotted filter papers, ice pack for whole blood enzyme assays, frozen condition for CSF neurotransmitters and other body fluid metabolites including amniotic fluid. All these together contribute to the complexity of the pre analytical variables.

The metabolites may also show an intra-individualas well as inter individual variability depending on dietary and clinical condition for eg: a patient with fatty acid oxidation defect may show an abnormal profile only in fasting state or sickness(1), while in a patient with an amino acidopathy or organic academia the metabolite profile will

depend on the clinical and fed status and eventual diet management and therapeutic intervention. Metabolic decompensation in a patient may also show an abnormal excretion of organic acids, alpha keto branched acids, dicarboxylic acids, aromatic acids etc. A detailed review of metabolic and non metabolic sources of organic acids is reported by Kumps A et al(2) emphasizes the need of detailed clinical, dietary and drug history for interpretation of metabolite report.

Analytical variables

The analytical tests for diagnosis of IEMshave transitioned from research laboratories of academic centersto clinical laboratories. The methods used are majorly developed in house and hence an extensive validation of the test is required before implementation as a clinical test. The laboratory should establish performance characteristics including accuracy, precision, sensitivity, specificity, reportable range and reference range for each test. The use of an internal standard in calibrator, control and patient sample for the tests performed on analytical platforms like HPLC, GCMS, TMSetc (3) is essential to correct for inter run variation arising due to sample preparation and analysis. The estimation of a reference parameter in addition to the required test would also be a good practice to correct for pre analytical variables. The commercial sources of reference material to be used as validated standards and the reagent to be used for estimation are very few. Hence laboratories have to prepare their calibration standards from weighed chemicals/ material available from companies like Sigma, Merck, Pierce and others. This may cause a batch to batch variation and hence a validation protocol with acceptable limits for each batch of calibrators/reagents must be pre-defined and followed.

The pathological condition of the patient may be associated with a prominent increase in a particular metabolite (substrate of the enzyme defect), detection of small quantities of a particular metabolite(formed by an alternate metabolic pathway or the product of the enzyme defect) and minor changes in a metabolite while monitoring the patient on therapy. In addition, most often a profile approach of analysis i.e. organic acids, amino acids, acyl carnitinesetcis used for detection of a group of disorders (4). Hence the assay conditions have to be optimized to detect several metabolites of a profile with analytical range spanning from the reference range of a metabolite to pathologic values which are several fold high.

Establishing reference range is desired but is very challenging particularly when invasive sample collection procedures like CSF sample, biopsied tissue, prenatal samples etc. are required. However, as and when possible the reference ranges should be established or validated with literature reference ranges. The laboratory should also take into consideration the age and gender dependent variations.

For qualitative tests both negative

and positive (as and when possible) control should be used with each batch of test results. In case of quantitative analysis like amino acid quantification and others Levy Jennings chartshave to be plotted along with other laboratory charts like temperature log, equipment maintenance and breakdown logs, reagent preparation and validation logs, assay performance records etc.

Personnel competence

The analytical methods used are technically demanding at the same time the result interpretation requires an in-depth understanding of metabolic pathways, clinical presentation and interferences due to drugs and other dietary sources. A combination of these two expertise is a challenge due to non-availability of formal training program for BGL laboratory personnel. A competency evaluation as well as an on job training and continuing education programs are essential for all staff members.

Proficiency testing

Participation in the external quality assurance programs relevant for the laboratory scope is mandatory. Various PT providers for BGL include

1) College of American Pathologists (CAP) for amino acid, organic acid, mucopolysaccharide and acylcarntitine analysis.
2) European Research Network for evaluation and improvement of screening, diagnosis and treatment of Inherited Disorders of Metabolism (ERNDIM) for quantitative amino acid analysis, qualitative and quantitative organic acid analysis, lysosomal enzyme testing and other metabolites.
3) National Tay-Sachs and Allied Disease Association (NTSAD) for Tay Sachs disease
4) Center for disease Control and Prevention, Newborn Screening Quality Assurance Program (NSQAP) for newborn screening etc.

The rare nature of several IEMs makes it difficult for any individual center to gain an expertise in diagnosis of all IEMs and hence an additional interlaboratory exchange for rare diseases would be desirable.

Post analytical variables

In case of urine samples it would be appropriate to report by normalizing to creatinine content rather than per volume of urine. The reporting of the test results should include a clear explanation of the test results including the interferences. The report has to be self explanatory and informative with appropriate reference ranges. The interpretations should also provide recommendations to the physician with respect to appropriate follow up and additional diagnostic and confirmatory testing when indicated.

Proper indexing of the positive patient's sample for future analysis is necessary. This may be required to confirm a diagnosis at enzyme/molecular level and also needed for reference material in the prenatal diagnosis in subsequent pregnancy.

BGL is a specialized subsection of clinical chemistry which is in its infancy stage in India. It is required

that the laboratories offering diagnostics for IEMs collaborate and define performance criteria so as to offer uniform protocols and quality standards to assure reliable test results.

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Doctor's Profile

Dr. Alpa J Dherai,
Ph.D
Consultant Biochemist

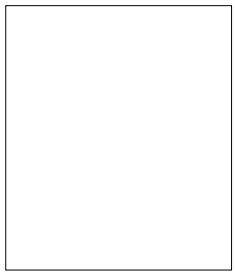
Professional Experience & Expertise
Dr. Alpa has an experience of around 13 years in clinical chemistry and has a specific interest in diagnosis of In-born errors of metabolism. She has to her credit the lead of setting up first accredited biochemical genetics referral laboratory in the country during her tenure at Sandor Proteomics Pvt. Ltd. Hyderabad (Sept 2007 - October 2011).
She underwent extensive training for diagnosis of In-born errors of metabolism, in Dept of Neurochemistry Massachusetts General Hospital, Boston; Department of Clinical Genetics, Erasmus Medical Centre, Rotterdam; Lab Genetic Metabolic Diseases & Academic Medical Centre, Amsterdam.

Research & Publications
She has around 20 publications in refereed journals and several presentations in National & International conferences.

Achievements
Dr. Alpa is a recipient of John Lawrence Fellowship & Travel training fellowship by European Research Network for Diagnosis of Inborn Errors of Metabolism (ERNDIM).
She has been a co-investigator in ICMR-National task force multi centric study for newborn screening for congenital hypothyroidism and congenital adrenal hyperplasia and High risk screening for In-born errors of metabolism. She has also been a principal investigator for several other DBT funded and in-house projects during her tenure at Sandor Proteomics Pvt. Ltd. Hyderabad.

dr_alpa.dherai@hindujahospital.com|| Ph: 022-24451515 Extn no. 7139

Quality Assurance in Surgical Pathology



Dr.Anita S.Bhaduri,
MD
Consultant Histopathologist

Accreditation in surgical/anatomic pathology is a relatively new concept in the economically competitive atmosphere of managed care. There will come a time of regulation that will require all surgical pathology centers to have a structured active program of quality assurance (QA) and quality improvement (QI) with the goals of enhancing patient safety, minimizing errors, ensuring timely delivery of reports and monitoring competence of lab professionals.

The face of surgical pathology has changed in the last few decades with technological advances in imaging. Evidence-based medicine is eliciting an increased interest in Surgical Pathology as the integration of best research evidence with clinical expertise and patient values.Pathology is an art as well as a science. Signout practices in Surgical pathology are based on observations and experience, therefore, subspecialization is imperative to address 'larger issues in smaller tissues'.The goal must be to provide the most scientifically accurate diagnosis but results can vary.

Surgical pathology processes are complex and as a result errors are inevitable, unavoidable but preventable in many instances. These are of varying types, significance and severity. The 1999 Institute of Medicine report 'To err is Human: Building a safer Health system' is based on the premise that all pathologists can make mistakes. Unexpected mortality and morbidity can result from Surgical Pathology errors that can affect patient outcomes.In surgical pathology, the primary impetus to assess and document quality practices(quality improvement) is related to a) professional and outcome-related components of diagnostic accuracy, (b) the usefulness of report content and(c) timeliness of communication(TAT). Since much of quality monitoring in surgical pathology is manually assessed, therefore speediness, reduced direct costs and impact of diagnosis on patient outcome are a measure of the laboratory's performance and result in satisfactory accreditation standards.

Analytic diagnostic errors have been the focus of scrutiny most often.But the QA and QI plan needs to include preanalytic and postanalytic phases as well.Discrepancy rates of errors vary from 7%-8% per pathologist but only 0.25% - 4% of these are potentially significant diagnostic discrepancies. An error, even when it affects patient care, is not necessarily evidence of substandard practice.

A) Preanalytic:

Incorrect or missing information forms 77% of all deficiencies. Specimen identification errors form 8-2%. Almost (40%) of the deficiencies relate to the chronic vexing issue of lack of clinical history and details on requisition forms with

9.4% being lack of indication of the source of tissue. These often result in delay in report completion in about a third of the cases (32%) as site of biopsy and clinical context are imperative in making a diagnosis based on observations in biopsied material..

It has been seen that 10% of changed diagnoses (``Amended reports'') in lung, ovary and small bowel are related to inadequate histories. Incomplete communication between clinicians and pathologists potentiates the opportunity for an erroneous interpretation with a poor diagnostic outcome for the patient. Technical factors like quality of biopsies, tissue fixation and processing and reporting can also contribute to differences in detection rates of diagnoses.

Various aspects of theSurgical Pathology laboratory's services must be monitored and evaluated to ensure that standards of quality are being met. Specific quality measures should have a component each of the following phases:

A. Preanalytical phase, e.g. specimen identification, accessioning errors, fixation delays, specimen delivery etc.
B. Analytical phase e.g.intra-operative diagnosis, peer review error rate, loss of specimen, mislabeling of slides,floaters,, turnaround time, external Proficiency testing etc.
C. Postanalytical phase e.g. transcriptional errors in reports, report delivery errors and Clinicians/patient satisfaction and/or complaints.

Proper use of ancillary test methods e.g. Immunohistochemistry, can improve patient safety and decrease diagnostic errors. IHC can be used for identification of tumor type in malignancies with a similar light microscope appearance but dissimilar cell lineages e.g. metastases of unknown origin or known breast cancer patient with a lung mass which may be primary or secondaries. However, IHC ordering patterns vary with the local practice and individual pathologists. Most histopathologists use IHC to increase diagnostic certainty, medicolegal concerns for peace of mind or even for Clinicians preferences for the same.

Examination of prior surgical pathology material in any given case is important information that should never be ignored.

Several labs also use 'frozen sections' as the principal means of providing a diagnosis for routine surgical pathology cases. It is worthwhile remembering that diagnostic accuracy is 97%-98% for frozen sections with a 0.1% chance of a clinically significant error happening.Sampling errors are an important source of missed diagnoses.

A mandatory second opinion in Oncology helps in reducing `interpretative errors".Disagreements with the 2nd opinion can be serious(<10%), substantial(20%) or minor(10%) as seen in worldwide published literature.Major discordance is of tumor type,pathologic stage and margin status.Minor discordance

relates to variations in grades ,subtypes etc that do not impact management.

QA tools in Surgical Pathology utilize data on amended reports,frozen-paraffin correlations,histo-cyto correlations,turn-around times and external QA testing along with peer review .Clinician/customer feedbacks are also invaluable tools if done objectively.

When an error is identified,this information must be directly and promptly communicated to the treating Clinician.Amended or revised reports are issued for change in diagnosis.Corrected reports are issued for change in information other than the diagnosis and addendums or supplementary report issued for additional information without any change in the original document.

Practice guidelines are developed by ADASP and CAP as an effort to improve quality and consistency with unified reporting formats. The only true gold standard for diagnosis in Surgical pathology is long term follow-up and response to therapy. However, Peer review has become the gold standard to judge diagnostic ``correctness'' in Surgical Pathology and acceptable performance.
Sentinel events are incidents in which there is significant patient harm or breach of known policies and procedures must be fully investigated,reviewed and change in policy/procedure made to address the problem.

When dealing with errors, the philosophy to be maintained should be that the error(s) could be anybody's and should be dealt with in the spirit of education and improvement of patient care and not as a means of condemnation.Most histopathologists doa wonderful job but `we can always do better'..

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Quality Management :

Dr. Asha Vaid

Total Quality Management (TQM) became an important management theory both in business and Industry, including health industry.
TQM philosophy is derived from earlier concepts of Quality Control and Quality Assurance. Definition of TQM is not limited to standard setting and quality control. It encompasses all aspects of organizational management with

continuous effort towards improvement. It concentrates on processes as well as products. It is centered on quality and long term success, patient satisfaction being a priority. TQM helps the lab to establish manage and monitor a testing process to provide an appropriate quality approach for its patient care services.

Total quality management (TQM) in Laboratories :

Feigenbaum (1) first described TQM in 1957. Since 1980 this has become an important management theory in industry and business. TQM takes into consideration the customers' needs. The customers' needs are defined through communication with physicians and other health care providers and helps the laboratory set up quality goals and criteria for an acceptable performance.

TQM philosophy is derived from earlier concepts of Quality control and quality assurance. Definition of TQM is not limited to standard setting and quality control, it encompasses with all aspects of organizational management with continuous effort towards improvement. It concentrates on processes as well as products.
It is centered on quality and long-term success, client satisfaction being a priority.

TQM help the lab establish, manage and monitor a testing process to provide an appropriate Quality approach for its patient care services.

The essential components of TQM - commitment & leadership

TQM is an approach to improving the competitiveness, effectiveness and flexibility of an organisation for the benefit of all involved. It is a way of planning, organising and understanding each activity, and of removing all the wasted effort and energy that is routinely spent in organisations. It ensures that the leaders adopt a strategic overview of quality and focus on prevention and not detection of problems.
TQM involves everyone and to be

successful, it must start at the top with the leaders of the organisation.

All senior staff must demonstrate their seriousness and commitment to quality, and middle cadre must, demonstrate their commitment, ensure they communicate the principles, strategies and benefits to the people for whom they have responsibility. Only then will the right attitudes spread throughout the laboratories..

Leaders must take responsibility for preparing, reviewing and monitoring the policy, plus take part in regular improvements of it and ensure it is understood at all levels of the organisation. Effective leadership starts with the development of a mission statement, followed by a strategy, which is translated into action plans down through the organisation. These, combined with a TQM approach, should result in a quality organisation, with satisfied patients and good results. The 5 requirements for effective leadership are:

- Developing and publishing beliefs, values and objectives, often as a mission statement
- Personal involvement and acting as role models for a culture of total quality
- Developing clear and effective strategies and supporting plans for achieving the mission and objectives
- Reviewing and improving the management system
- Communicating, motivating and supporting the lab staff and encouraging effective employee participation

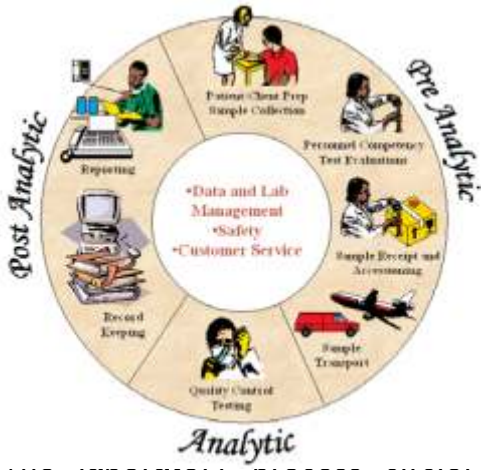
The TQM framework involves

- Quality Laboratory Processes (QLP)
- Quality Control (QC).
- Quality Assessment (QA).
- Quality Improvement (QI)
- Quality Planning (QP)
- Quality Goals

Quality Lab Processes : This would describe the Polices, procedures, personnel, standards, Laboratory methods and System operating procedures for tests.
Procedure for monitoring the process. A good QC system helps to prevent detect and correct problems. Statistically Quality control monitors analytical performance in relation to accuracy and precision. This involves external quality control as well as internal quality control.

Quality Assurance Monitors the overall performance. This includes both analytical as well as customer satisfaction which can be done by objective feedback. This should address the pre analytical, analytical and the post analytical phase. Turn

around time, patient preparation, sample receiving, feed back from doctors and patients can serve as an indicator of QA of the pre and post analytical phase. External Quality Assurance and proficiency testing, monitor analytical quality.



(reproduced from John Elliot PPTC, Wellington NZ).

Quality improvement : is the outcome of QC and QA. It helps to identify the source of the problem, also leads to how to tackle the problems, followed by monitoring the problems till it is solved.

Quality planning : is a prerequisite to quality assurance. It establishes and validates process from both analytical quality as well as customer needs. It designs processes when one needs to adopt new methods or select new instrumentation. Quality planning also helps in designing appropriate QC programs. It makes sure that Quality aspects are not neglected and added at the last minute.

Quality Control Goals: Represents the requirement that must be achieved to satisfy customer needs.

For analytical quality the requirement is to provide test results that are correct within the stated limits. Ultimately it is not a sample but the patient at the end of it who gets accurate results.

TQM Benefits :

TQM adds to the operation costs but in return ensures quality in the overall process. Since it starts at the top an active and effective leadership with involvement gives an impetus to the empowered staff. The aim is to reduce errors and thereby costs and to do things right the first time. The overall operation is transparent to all the staff. All this