INTRODUCTION TO QUALITY CONTROL & QUALITY ASSURANCE IN THE CLINCAL LABORATORIES.

- **Daily Practice of Quality**
    - School & Education
    - Clothes and dresses selection
    - Restaurants & Food
    - Cars & Vehicles
    - Hotels & Accommodation
    - Repairs & Maintenance
    - Household Appliances & Furniture

- **What is Quality?**
    - It is the best possible expected outcome of an effort under given conditions and terms of skill, experience, financial and available resources.
    - [Customer Satisfaction]

- **Quality in the Healthcare Field.**
    - **Targets (customers) of the healthcare team:**
        - The Patient (human beings with vital background of responsibilities, ties, relations & connections)
        - The Community
    - **The aim of the healthcare team:**
        - to provide quality patient care
        - To provide quality health service to the community

    - **The healthcare team:**
        - All those who are involved in providing health care directly or indirectly including; doctors, nurses, technologists, technicians, radiologists, porters, auxiliary staff and administration.

- **QC, QA, CQM & TQM**
    - QC (Quality Control)
        - Is the type of system/s or programs that are specifically applied to ensure the conformity of the results (outcome, products) to established criteria or standards.

    - QA (Quality Assurance)
        - Is the total efforts and activities by a group of specialists to achieve quality results (products, outcome)

    - CQM (Continuous Quality Monitoring)
        - Is the continued specified checks (according to established criteria) on the various components that are involved in the production of quality results (products, outcome)

    - TQM (Total Quality Management)
        - Is the continued observation and monitoring by the institution of all sections and groups under a specific task or mission to meet the set Goals of Quality for the institution.

The function of the clinical laboratory

- To carry out tests and investigations on patients specimens upon the doctors request and produce meaningful and timely results which help in the diagnosis of disease, treatment and management of the patient.

  - Meaningful results
    - » Reliable results

Accurate : close to the real "true" value
Precise : similar results if repeated on same specimen

- » Expressed in Acceptable units

(quantitative: SI, conventional, qualitative and semi-quantitative)

  - Timely results
    - » Available when wanted

routine urgent

- Components of QA Program
  - Pre analytical
    - Analytical
      - Post analytical

- To obtain meaningful and timely results ALL components of the QA Program MUST observe and adhere to the specific instructions set by the lab regarding all the aspects included in the specific component.

- Pre analytical stage
  - Outside the control of the lab
  - Clear and accurate instructions must be given to personnel
  - Involves: doctors, nurses, patient, phlebotomist, messenger (porter)
  - Includes:
    - request for investigation,
    - request form,
    - patient instruction,
    - patient preparation,
    - specimen collection,
    - handling
    - transportation

  - The quality of the result is dependent on the quality of the specimen.

- Analytical stage
  - Within the control of the lab
  - Involves technicians, lab aids, technologist, supervisor, lab manager, lab director, engineers, clerk, secretary, administration
  - Policy & Procedure Manuals
  - Includes:
    - Specimen reception and booking
    - Centrifugation, separation, aliquoting, storage
    - Equipments and instruments:
      - Types
      - Priming & calibration

    - Care & maintenance
    - evaluation
- Procedure of analysis
    - Type (spectrophotometer, turbid metric…)
    - Interferences
    - Specimen requirements
    - Sensitivity, specify
    - Accuracy and precision
- QC system
    - Heart of the QA program
    - No QC No results
    - Checks for errors
    - QC materials (human, animal sera….)
    - Systems for quantitative results (Levy-Jennings Chart, CuSum, Multi Rule, Replicate Analysis, Delta Check)
    - Systems for qualitative results
    - System for semi-quantitative results
    - Automated or manual QC
    - Recording of QC and actions taken

- Chemicals, water & kits
    - Chemical reagents type (Ultra-pure, Analytical)
    - Reagent preparation, handling and storage
    - Water types and purification systems
    - Kits evaluation
- Safety
    - AIMS OF SAFETY
    - Physical
    - Chemical
    - Health
    - Fire
    - Radiation
    - General
    - Safety equipments
    - Waste disposal
    - Rules and regulations
    - ALWAYS PRACTICE SAFETY
    - NEVER EXPOSE YOURSELF OR OTHERS TO HAZARDS
- Personnel
    - Categories
    - Qualifications
    - Experience
    - Motivation
    - Dedication
    - Salary & allowance
    - Performance evaluation
    - Promotion
    - Discipline & dismissal

- Post analytical stage
    - Mostly controlled by the lab.

- Involves: technologists, clerks, secretary, lab supervisor, lab consultant, lab director, porter, nurse, doctor
- includes
  - Results acquisition
  - Use of QC for results validation
  - Results reporting
    - (result form, machine printout, manual writing, routine & urgent requests)
  - Filing
  - Queries and complaints

ALWAYS THINK AND PRACTICE QUALITY ASSURANCE

CONSIDER THE PATIENT AS YOUR CLOSE FRIEND OR RELATIVE.

QC Material

- Manufacture
  - In-house
  - Commercial
- Source
  - Human
  - Bovine
  - Porcine
  - Murine
  - Equestrian
  - Avian
- Type
  - Whole blood
  - Serum
  - Plasma
  - Aqueous
  - Synthetic
  - Spiked
  - Stripped
- Quantitative measure
  - Assayed
  - Un-assayed
- Levels
  - High abnormal
  - Normal
  - Low abnormal
- Dispatch
  - Batch No.
  - Lot No.
  - Expiry Date
  - Shelf life
  - Biohazard
  - Lyophilized
  - Liquid

- Frozen
- Powder
- Storage

QC MATERIAL CHECK

- New batch arrives 30 days before the expiry or finish of the previous lot
- Enough quantity to last for the whole period of the control use (3-12 months)
- Same manufacturer; Batch/Lot numbers, Expiry Date, Level
- For blood gasses, pH, Na, K, Cl check for 5days (4times daily)
- For other analytes for 20-30days
- Write down a schedule (number of run, days, date, time, personnel)
- Treat exactly as the patient sample (operator may not know the identity)
- Enter results on a table
- After the check period calculate: mean, SD, 2SD, 3SD & cv
- If any of the values exceed 3SD then discard and recalculate
- Check against manufacturer's values
  - Obtained mean within ±2SD of the manufacturer's mean
  - Obtained SD similar to or close to the manufacturer's SD
- Plot a Levy-Jening Chart using obtained values(mean, ±1SD, ±2SD, ±3SD)

Application of QC Systems (L-J Chart & Multi-Rule Systems)(Quantitative Results)

- Use two levels of control (L/N, L/H, N/H)
- Ensure that fro each level: same manufacturer, Batch/Lot No, Expiry Date
- Organize analysis into runs
- Each run at specified daily times
  - 1st Run 9 am
  - 2nd Run11 am
  - 3rd Run 1 pm
  - 4th Run 2:30pm
- Place controls in the same positions in all runs
  - Beginning
  - Middle
  - End
  - One in the beginning one at the end
  - Lower level then higher level (L-N; L-H; N-H)
- Plot values on respective chart as the results for the control appear
- Check for any violations of the control rules
- Check for trends, shifts and outliers
- Follow the decision flow chart for manual or automated procedures

Westgard Multi Rule System Applicable to Quantitative Lab Results

Rule	Explanation	Error type	Action
$\mathbf{1_{2S}}$	One control value above or below 2SD	RE/SE	Warning
$\mathbf{1_{3S}}$	One control value above or below 3SD	RE	Reject
$\mathbf{2_{2S}}$	two control values above or below 2SD (consecutive values within control (across runs), within the same run (across control materials)	SE	Reject
$\mathbf{R_{4S}}$	One control value above 2SD in one level and one control value below	RE	Reject

	2SD in the second level in the same run (across control materials)		
4_{1S}	Four consecutive control values above or below 1SD (within control) (across control)	SE	Reject
10_x	10 consecutive control values at one side of the mean (within control) (across control)	SE	Reject

Using the multi-rule system

- Manual procedures;(linear approach)
  - Apply if control values exceed ±2SD
  - Sequence of rules;
    - $1_{3S} \rightarrow 2_{2S} \rightarrow 4_{1S} \rightarrow 10_x \rightarrow R_{4S}$
- Automated Procedure (branched approach)
  - Sequence of rules
    - If control value > +SD OR < -2SD;
      - $1_{3S} \rightarrow 2_{2S} \rightarrow R_{4S}$
    - If control value is within ±2SD;
      - $4_{1S} \rightarrow 10_x$

Modifications and alternative approaches

- Computerized automatic check (built-in QC charts and multi-rule system)
- Computer QC software programs (for both manual and automated procedures)
- Combined two levels chart (each level values with different colour)
- Combined vertical /horizontal chart (one level horizontal and the other vertical) (square boxes representation)
- Analyte specific rules (depending on allowable error rather than SD)
  - Starting considerations according to analyte
    - $1_{3.5S}$ for glucose, Na, K, BUN
    - $1_{2.5S}$ for albumin and chloride
- Average of duplicate or triplicate values and then using the mean
    - Hormones, Ca, Mg
- Restriction of the multi-rule to detect large errors
  - Omitting the use of 4_{1S} & 10_x
  - Inclusion the probability of randomness of errors occurrence
  - Modifying some of the rules;
    - 2 out of 3 consecutive runs violating the 2_{2S}
    - 6 consecutive control values above or below 1SD in one control (6_{1S})
    - Using only the 1_{3S} for RE detection and 2_{2S} for SE detection
  - Combining the multi-rule with other QC systems e.g.CuSum or Delta Check

Actions Taken if Error or violation Occurs

- Check controls
  - Repeat control
  - Reconstitute new vial
- Recalibrate
- Check Possible source according to type of errors then correct & repeat run
  - Reagents, calibrators, controls Expiry date, contamination, deterioration, storage, reconstitution
  - Pipettes and pipetting
  - Temp, vibration, humidity, air current
  - Personnel experience, skill

- Instrument malfunction;
  - Electrodes, membranes, pump, electronic circuit, lamp, fuse, tubings, connections, electrical supply, ventilation

Conclusion

- Every lab must have applicable QC & QA Systems
- NO QC → NO RESULTS
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