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Control of analytical quality using pt data

Patient data → Additional info in monitoring quality of lab. analyses

→ time consuming
→ not sensitive enough to serve only mean of QC

→ But may ~~provide~~ detect problems & may not be evident ~~in~~ conventional QC system.

① Individual patient results
② Multiple pt results.

① Individual patient's results:
- most direct form of QC
- less sensitive

→ done by clinical co-relation of test result & other info of pt → surgical data
→ response to therapy
→ autopsy data.

② Clinical correlation:-
high volume, core laboratories
↓
Impractical to correlate all test results clinically
↓
clinicians ordering test are better to evaluate test result acc. to their pt. situation

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ex → Identificat^{n} of highly impossible test
e.g. low bilirubin in highly jaundice.
↓
clinicians should be encouraged to report such discrepancies.

(2) Co-relat^{n} c other laboratory test →

Single test → implausible to ~~judge~~ corelate clinic
Combination of test → at same time.
↓
possible to identify error

ex → (1) S. urea = 200 mg/dl
S. creatinine = 0.5 mg/dl
↓
Indicate possibility of error.

(2) Thyroxin - TSH level
↳ (1) Negative feedback of th
↓ secret^{n} of TSH
↓
~~S. T4 ↑ → 0.8 mg/dl → ↓ TSH~~
↑ T4 level leads to ↓ TSH level
↳ exceptions = 2° hyper thyr

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(5) Intralaboratory duplicates :- / Retain Sample.
↳ simple QC procedure
↳ used when stable QC material are not avail.

Sample
↓
devided in 2 aliquots
↓
Duplicates analyses
↓
diff. b/w duplicate are plotted in range type of control chart → control limit are calculated from SD of difference

error detect°

Duplicate analysed by same method
↓
detect random error
↓
Not adequate to ensure accuracy of method.

Duplicates analysed by diff. method
↓
detect both random and systemic error
↓
can not differentiate type of error and if method has error
↓ need of recalibration.

(4) Delta check c̄ previous test Result.

Comparision of test value c̄ value obt. on previous sample from same pt

↓

Identify error in specimen identificat^n

→ ~~Expectable~~ Expected variability depends on analyte and time interval b/w 2 analysis.

Example → Ladenson define deltacheck limit based on 3 day interval in %.

for albumin → expected variability / del check limit = 20%.

(5) Limit check

↳ Review to check the test results within physiological range compatible c̄ life.

↓

Detect clerical error → transposed digit
→ misplaced decimal p

example → S.Na = ~~1.35~~ 13.5 mmol/L

↓

misplaced decimal place of 135.0

↓

Implementing limit check software

↓

prevention of autorelease of reports out of defined limit.

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(II) Multiple Patients data:-

Test distributation statistics

- Distribution of test results from large no of patients → useful in detecting any systemic error → thus used in conjunction c̄ stable control materials

- Includes source of variance
  - Demographic → ex → (1) male hospitalised → (1) male female ratio → (2) ~~Ratio of hospitalised pt to OPD~~
  - Biological
  - Pathological
  - preanalytical → tourniquet time, specimen storage
  - Analytical

→ This statistics are more useful when pt are segmented into groups.
e.g. → different clinics
→ " phlebotomist
↓
- Subgroup have ~~similar~~ smaller c̄in group variance
- Smaller c̄in group variance
↓
better ability to detect systemic error.

⇒ Statistical methods or approaches for monitoring pt means

(1) Mean of Normal / Average of Normal (AON)
↓
establishing limit for reference value
(trimming pt data)

↓

value outside the limits are eliminated

(3) Median of values:-

↳ more sensitive than mean

(4) Weightage based mean:-

based on % of patient in each category.

↓

higher sensitivity for error detection.

Or → Albumin / total protein limits in any hospital pt → lower than (N) individuals.

(5) ~~Rudd's algorithm:-~~

(6) Running Mean of values.

↓

Average of mean of previous batches results.

↓

large batch size → provide ↑ no. of specimens → ↑ time

↓

detect instrument mal

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⇒ Combined use of liquid control and moving average of patient values for QC

liquid control material → Smaller variances

patients test data → larger variances (Inter, Day)

↓

when this variances are controlled or adjusted, they provide additional supplement to liq. control

↓

longer the patient data of group is smaller the variance.