Total Error (TE)

vs

Total Allowable Error (TEa)

Practical View in Clinical Laboratory

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Does laboratory always do “Error” ?

OR - Is it acceptable variables ?

- **Biological Variation**
  - **With in Person**
    - Time ——————————————->>> RBS , Urine Glucose, Osmolality
    - Water Intake / Fluid Infusion >>> Haemoglobin , PCV , Electrolytes
    - Sleep ——————————————- >>> Cortisol , ALT , AST
    - Exercise ——————————————->>> Creatinine Kinase , Lactic acid
    - Diet / Addiction / Alcohol ——>>> Triglyceride , Urea
  - **Between in The Persons**
    - Age ——————————————->>> Cholesterol / Creatinine /
    - Geographical Location ———>>> Semen Analysis (Volume , Motility), Vitamin-D , Vitamin - B12,
    - Altitude ——————————————->>> RBC, WBC, Platelet Count
    - Ethnic ——————————————>>> Haemoglobin Variant (Indirectly HbA1c)

Laboratory has Always Question .
Is it Error or Variability ?

- **Pre-Analytical Variation ====== Error / Variability**
  - **Preparation & Collection**
    - Non Fasting Sample for FBS , Lipid Profile
    - No Mid-stream Urine for Urinary Examination
    - Urinary Sampling during Menstrual Bleed
    - Wrong Vacuttee
    - Wrong Proportion for Anti-Coagulant Test

Laboratory has Always Question .
Is it Error or Variability ?

- **Analytical Variation.** ====== **Error / Variability**
  - **Different Method** = **Difference in Reference Range**
    - **LDH** = Pyruvate to Lactate / Lactate to Pyruvate
    - **Creatinine** = Wet Chemistry / Dry Chemistry / Enzymatic
    - **Immunology Analyte** = CLIA / MCLIA / eCLIA / ELISA
  - **Analyzer With Different Calibrator**
    - Difference in Calibrator Traceability

What are the "Real Heros of Total Error" ?

Think,

Are their part of Error or Variability ?

What Is it ???????

Random Error

Systemic Error

OR

Biological Variation of Clinical Laboratory

- **Haemato-analyzer - Laser Light In-stability**
- **Sample Aspirator In-stability**
- **Sample / Reagent Syringe Pump In-stability**
- **Electric Supply In-stability**
- **Sample In-stability**
  - During Transport
  - In Accession Area
  - In Analytical Area
- **Consumable In-stability due to**
  - In stability of Temperature of Refrigerator / Analyzer

What are the "Real Heros of Total Error" ?

Think,

Are their part of Error or Variability ?

What Is it ???????

Random Error

Systemic Error

OR

Biological Variation of Clinical Laboratory

- **Inaccuracy of Syringe Pump of**
  - Sample
  - Reagent
- **Consumable deterioration due to temperature**
  - Reagent
  - Sample
  - Calibrator
  - Quality Control

Moral of The Story

Variable are Allowed , Hence , It is Included in Total Allowable Error TEa

Error are Not Allowed , It is does not included in Total Allowable Error - TEa

How laboratory can measure “Total Error” ?

Systemic Error (Bias)

EQAS Bias / Calibration Bias / Reagent Lot Bias

+

Biological Variation (Non Detectable)

Delta Check / History / Experience

+

Random Error (SD / CV%)

IQC Variability

Total Error (TE)

Laboratory can measure their Total Error (TE) by

TE % = Bias % + 2CV%

TE = Bias + 2SD

Laboratory TE < TEa (Total Allowable Error) as per CLIA / Westgard / CAP

TE % = Bias % + 2CV%

It will be for individual parameter / Not Common for Laboratory

- **Bias% can be measure with**
  - **Reference - Calibrator Material** , But **NO One Use It**
    - Best Choice if Material is traceable
    - Compare with reference value
  - **EQAS - Proficiency Testing**
    - Should be many many participants (> 1000)
    - Same Methodology
    - Same matrix for comparison

Bias % / Bias

It will be for individual parameter / Not Common for Laboratory

$$\text{Bias \%} = \frac{(\text{Your Analyte Value} - \text{Reference Value})}{\text{Reference Value}} \times 100$$

$$\text{Bias} = \text{Your Analyte Value} - \text{Reference Value}$$

If **EQAS** is used for measuring bias% ,

Reference Value = Mean for Comparison in EQAS

When to use Bias % & Bias ??

SD - Standard Deviation / CV% - Coefficient Variante

It will be for individual parameter / Not Common for Laboratory

- **SD / CV% can be measure with**
  - **IQC Material**
    - Better to Use Multiple Level of IQC
    - SD / CV% - Variability might be different at different level of concentration.
    - **It is Worst - As We need to measure variability of patient's sample analysis.**
    - **But Only Option Of Measuring Coefficient Variance of The Patients Sample**

TE is incomplete with out Bias % & 2CV%

Turning
From Total Error To Total Allowable Error

TE < TEa (Total Allowable Error)

Total Allowable Error

How to Find ????

How to Use ?????

As Per Guideline
Total Allowable Error (TEa) is pre-defined

“ Allowed “ = TEa define How much “Level Maximum Error” Can be Allowed

Finding it From Following / Guidelines

- Westgard Guideline
- CLIA = Clinical Laboratory Improvement Amendments (CLIA)
- CAP = College of American Pathologists
- https://datainnovations.com/allowable-total-error-table/
- https://www.westgard.com/clia-and-quality-regulation-requirements/quality-requirements/2024-clia-requirements.html

Can Laboratory "Control TE" With use of TEa ?

$$TE\,\% = Bias\,\% + 2CV\%$$

$$TE\,\% = Bias\,\% + CV\% + CV\%$$

$$TE\,\% = Inaccuracy + Imprecision + Imprecision$$

$$TE\% = 3 \times Variability$$

$$Variability = TE\,\% / 3$$

Can Laboratory
"Control TE"
With use of TEa ?

Inaccuracy >>>Bias % >>> EQAS >>>> Maximum Frequency Once In Month

Imprecision >>>CV % >>>>IQC >>>>>>>> Minimum Frequency Once In Day

Hence , Difficult to Control Event, Which is evaluated once in month.

Better to Ignore Bias % for Few Months = Keep It "Zero"

TE % = Inaccuracy + Imprecision + Imprecision

TE % = Zero + Imprecision + Imprecision

TE% = 2 x Variability

Variability = TE % / 2

Example

L-J Chart of IQC Level -1 for Serum Glucose

- Assigned Mean of Glucose : 100 mg%
- Assigned 1- SD of Glucose : 6 mg%
- Cumulative CV % of Last 1 Month Data : 5 %

Last Month RIQAS - EQAS

- Mean for Comparison : 200
- Laboratory Value : 204

Calculated - Find

TE % =

TEa % =

Choose Formula

$$TE\% = Bias\% + 2CV\%$$

$$Bias\% = \frac{(\text{Your Analyte Value} - \text{Reference Value})}{\text{Reference Value}} \times 100$$

$$CV\% = (SD \times 100) / Mean$$

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Calculated - Find

TE % = [(204-200)x100]/200 + 2x5 = 2 + 10 = 12 %

TEa % = ???

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Calculated - Find

TE % = [(204-200)x100]/200 + 2x5 = 2 + 10 = 12 %

TEa % = 8 % as per CLIA

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TEa % = 8 % as per CLIA

Is Assigned 1-SD Correct ???

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Calculated - Find

TE % = [(204-200)x100]/200 + 2x5 = 2 + 10 = 12 %

TEa % = 8 % as per CLIA

Correct (Maximum Allowed) SD

Reverse the formula

TEa % = Bias % + 2CV%

CV % = (TEa%-Bias%) /2

(SD x 100) / Mean =(TEa %-Bias%) /2

SD x 100 = [(TEa%-Bias%) x Mean] / 2

SD = [(TEa%-Bias%) x Mean] / 200

Maximum Allowed SD = [(8-2) x 100]/ 200 = **3**

Maximum Allowed SD = 3 in Glucose L-J Chart

Reverse the formula

TEa % = Bias % + 2CV%

TEa % = Zero + 2CV%

CV % = TEa% /2

(SD x 100) / Mean = TEa % /2

SD x 100 = (TEa% x Mean) / 2

SD = (TEa% x Mean) / 200

Maximum Allowed SD = (8 x 100) / 200 = 4

Maximum Allowed SD = 4 in Glucose L-J Chart

(With Expected Bias % = Zero)

Does assigned SD in L-J Chart make impact on TE?

More SD in L-J chart ,than Maximum Allowed SD

Allowing IQC Outlier to fall under Westgard

False Presumption of Precision

At The End of the Months

Cumulative CV % >> Higher / Lower

TE % >> Higher / Lower

Does assigned SD in L-J Chart make impact on TE?

More SD in L-J chart ,than Maximum Allowed SD

Allowing IQC Outlier to fall under Westgard

False Presumption of Precision

At The End of the Months

Cumulative CV % >> **Higher** / Lower

TE % >> **Higher** / Lower

Any Thing Cross The Limit >>>Legally Prohibited

Sorry If
I Crossed Limit of Time
or
I Wasted Your Time.

As

Time is Costly Asset.

I Heartily Appreciate You All
for
Spending to Your Valuable Asset With Me

-:Thank You Very Much :-