Pharmaceutical statistics

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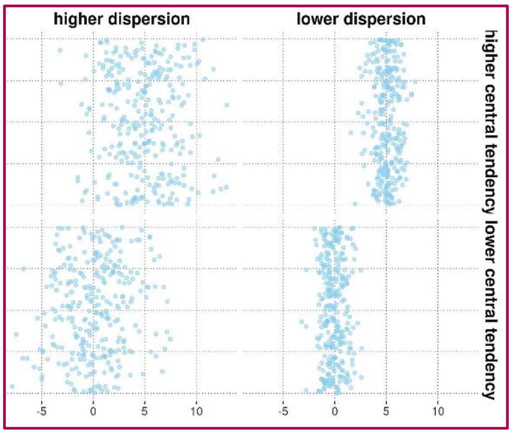
Descriptive statistics

- ***Statistics***: collection, organization, summarization and ***analysis*** of data, and the drawing of inferences about a body of data when only a part of the data is observed.



- With interval scale (*continuous measurement*) data, there are **two** aspects to the figures that we should be trying to describe:
  - ➢ How *large* are they? *'Indicator of **central tendency**'*
  - ➢ How *variable* are they? *'Indicator of **dispersion**'*

- Indicator of ***central tendency*** describes any statistic that is used to indicate an ***average value*** around which the data are clustered

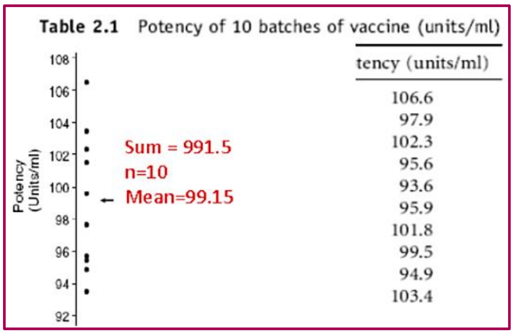
- Indicator of ***dispersion*** describes how wide the data are scattered around this central tendency indicator.
  - ★ Example 1:
    - FBG for two sets of patients as follows:
      Set A: 84, 85,89, 89, 93, 94.   Set B:72, 82,89, 89, 96, 106.
    - Which is larger? The same.
    - Which is more variable? Set B

  - ★ Example 2:
    - ✓ Set A: 10, 20, 30, 40, 50   Mean = 30
    - ✓ Set B: 30, 29, 28, 31, 32   Mean = 30
    - ✓ The difference between the two sets is the dispersion (set A is more variable than B).

- **Three** possible *indicators of central tendency* are in common use:
  - ➢ ***Mean*** المتوسط الحسابي
  - ➢ ***Median*** الوسيط
  - ➢ ***Mode*** المنوال

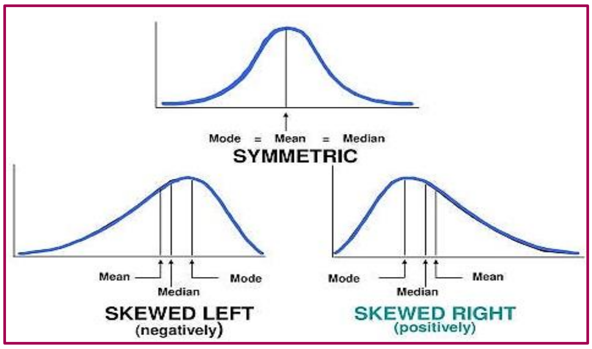
Mean

- The usual approach to showing the central tendency of a set of data is to quote the average **or** the 'mean'.
  - ★ Example:
    - ✓ Potency data of different vaccine batches.
    - ✓ Each batch is intended to be of equal potency, but some manufacturing *variability* is unavoidable.
    - ✓ A series of 10 batches has been analyzed and the results are shown in the following table.



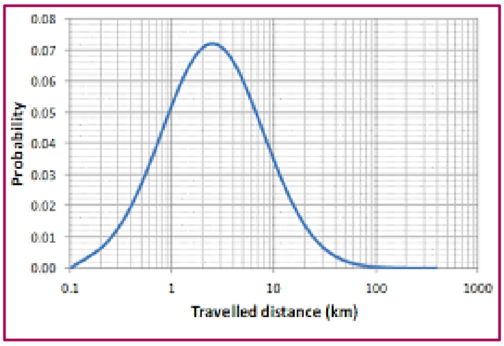
- ***Types of mean:***
  - ➢ *Arithmetic mean*
  - ➢ *Geometrical mean*
  - ➢ *Harmonic mean*

- ***Arithmetic mean***

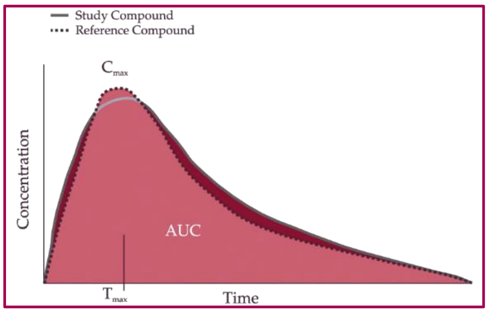


  - For a *population* of **N** values: X1, X2, X3, …., X_N
    - ✓ The mean is calculated as: $\mu = \frac{\sum_{i=1}^{N} Xi}{N}$
  - For a *sample* of **n** values: x1, x2, x3, …., x_n
    - ✓ The mean is calculated as: $\bar{x} = \frac{\sum_{i=1}^{n} xi}{n}$
  - Arithmetic mean represents the *balance point* of the distribution.
  - The arithmetic mean has the following properties:
    - *Uniqueness*, for a given set of data there is ***one and only one mean***.
    - *Simplicity*, easy to understand and computed.
    - *Not robust to extreme values*, it is affected by each value in the data.
  - ★ Example:
    - For the values: 5,10,15 mean=10
    - For the values: 5,10,150 mean=55

- ***Geometric Mean:***
  - It is the anti-log of the average of the logarithms of the observations.
    - *GM= anti-log* $[\frac{\sum_{i=1}^{n} logxi}{n}]$



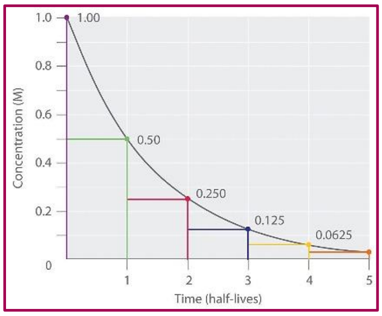
  - Used when the frequency distribution is highly skewed to the right or left.
  - ★ Example:
    - For the values 50, 100, 200.
    - The ***GM*** = *Anti-log* $[\frac{log50+log100+log200}{3}]$ = ***100***
    - While the arithmetic mean is ***116.67***
  - Is meaningful for data with logarithmic relationships as in the case of the current procedure in *bioequivalence studies* where the ratios of log-transformed parameters are compared (log (**AUC**), log (**Cmax**)).
  - It is less influenced by extreme values (outliers) and is particularly *useful for data that grows exponentially* ***or*** *is highly skewed.* (Taking the log of the variable values can normalize the data).
  - ★ Example:



    - The study of bioequivalence of generic drug:
    - $\frac{GM\ generic}{GM\ brand}$*100% should be 80-125% to be accepted*
    - The variables are:
      - ○ AUC ($\frac{AUC\ generic}{AUC\ brand}$*100%)
      - ○ Cmax ($\frac{Cmax\ generic}{Cmax\ brand}$*100%)

- If we have 30 volunteers (the min. no. of volunteers)
- We give them the generic drug to observe its conc. in the blood, our purpose is to resemble the conc. of the brand drug regardless of the toxicity.
  - ***Arithmetic mean ≥ Geometric mean for the same observation***

- ***Harmonic Mean***
  - It is the *reciprocal* mean of the reciprocal of values or observations.
  - ***HM*** $= n/\sum(\frac{1}{xi})$



★ Example:

- The half-lives of a certain drug in 3 subjects were 2, 4, 8 hrs. determine the harmonic mean half-life for this drug.
- ***HM*** $= 3/(\frac{1}{2}+\frac{1}{4}+\frac{1}{8})$ = ***3.429***
- While the arithmetic mean is 4.667 hrs.

- If we want to calculate arithmetic mean we ignore that half-life is obtained by reciprocal relationship we will have higher answer than harmonic but harmonic mean is the correct mean to be calculated.
  - ✓ How do we determine half-life? $t_{0.5} = \frac{-0.693}{slope}$
- *Harmonic is used with rates usually.*

★ Example:
If we have two cars with different speeds
Car 1 speed = 60km/h and it drove for 2 hours
Car 2 speed= 120km/h and it drove for 1 hour

- ***Harmonic mean*** $= 2/(\frac{1}{60}+\frac{1}{120})$ = ***80km/h***
- The harmonic mean gives the average speed of the two cars over the combined time they traveled. While the arithmetic mean of their speeds would be 90 km/h, the harmonic mean (80 km/h) is *more accurate* because it accounts for the different times each car spent traveling.
- The harmonic mean is used with the total time (3 hours) to calculate the total distance: 80 km/h×3 hours=240 km (This matches the total distance traveled by the two cars).

- *Weighted Harmonic Mean:* Applies when different observations have varying importance or impact, like different time contributions in the example above.
- *Weighted arithmetic mean:*

★ Example:

- If we have 40 Females & 20 Males

  Avg. F grades = 75

  Avg. M grades = 85

- What is the Aug. for the class?

  Avg class = $\frac{40}{60} * 75 + \frac{20}{60} * 85 = 78.3$

- ***Harmonic mean < Geometric mean < Arithmetic mean***

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