Pharmaceutical statistics

2025-2024

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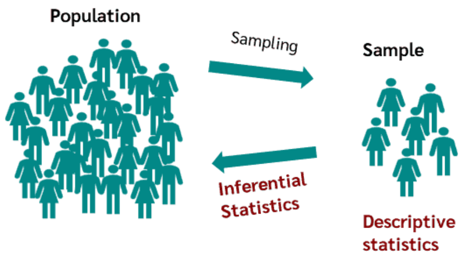
ARKAN ACADEMY

Introduction

- ***Definition***

  - ***<u>Statistics</u>*** is the field of study concerned with:
    - ✓ The <u>collection</u>, <u>organization</u>, <u>summarization</u> and <u>analysis</u> of data (*Descriptive statistics*)
    - ✓ The drawing of <u>inferences</u> about a body of data when only a part of the data is observed (*Inferential statistics*).



✦ Example 1:

n=45 (students no.) The variable of interest is the *students' marks*

- The first step would be *collection* of Data (but this data is useless).
  Students' marks: 51, 72, 96, 55, 76……
- The second step is *organization* of data (ordered array)
  The ordered data: 51, 55,72, 76, 96……
- *Summarization* by making intervals.
- Then the *Analysis:* you must determine:

Interval	***frequency***
0 - 20	1
21- 40	2
41 - 60	7
61 - 80	17
81 - 100	18

- ✓ The measurements of ***central tendency***: mean, median, mode
- ✓ The measurements of ***dispersion***: standard deviation

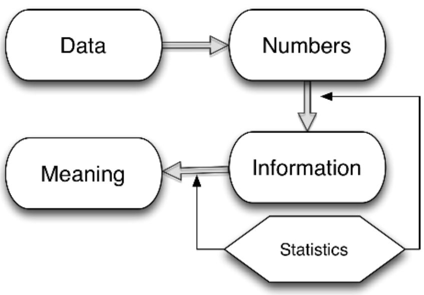
✦ Example 2:

To study the effect of smoking on the UJ student's performance.
The population N: **UJ's students**
We can take a sample from the students and use the statistics to have ***inference*** about the population.

Measure	**Population Parameter**	**Sample Statistic**
Mean	μ	$\overline{X}$
Variance	σ^2	S^2
Standard Deviation	σ	S

- ***Data***

  - Data is the <u>raw material</u> of statistics; we may define data as *numbers.*
  - There are ***<u>two</u>*** kinds of numbers that we use in statistics:
    - ✓ Numbers resulting from taking a ***measurement*** (Cmax, tablet hardness, patient temperature etc.).
      (These measurements can be nominal, ordinal, interval, ratio)
    - ✓ Numbers that result from a process of ***counting*** (patients discharged from a hospital per day, tablets produced by a certain process per shift etc.).



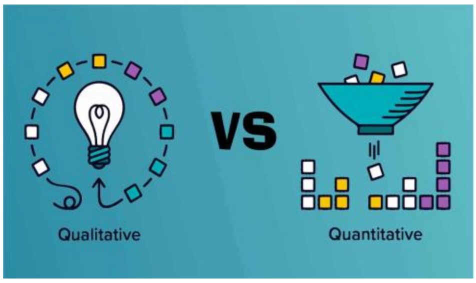
  - Data may be obtained from one or more of the following ***<u>sources</u>***:
    (Routinely kept records– Surveys– Experiments– External resource)

- ***Variable***

- A *characteristic* monitored, capable of taking *different values* (diastolic blood pressure, heights of students, hardness of tablets).

- ***Variables can be classified to:***

1. ***A quantitative variable*** is one that *can be measured* in the usual sense (heights, weights, drug content, plasma concentration at some time point).
   They are usually *continuous random*, however; can be discrete (UJ grading system).



2. ***A qualitative variable*** is one that *cannot be measured.*
   It can be described or *categorized* (gender, race/ethnicity of patients, discoloration in produced tablets).
   Qualitative variables can be counted to produce frequencies (*discrete variables*) like the frequency of a certain race or the number of discolored tablets.

✓ ***Random Variable***

Whenever the values obtained from a measurement arise because of chance factors, so that they cannot be exactly predicted in advance

- ***Variables can be classified to:***

✓ ***Continuous*** random variables: so that they take an infinite number of possible values with ***no gaps***. (are usually measurements)

✦ Examples:

✓ Tablet weights between 290 and 300 can be 290, 291, 292 ....299, 300 or 290.1, 290.2........299.9, 300 depending on the sensitivity of the balance.

✓ Drug concentration, height and temperature, weight.

✓ ***Discrete*** random variables: may take on only a countable number of distinct values and ***there are gaps*** between values, such as 0,1,2,3,4, ...

✦ Examples:

Discrete random variables usually (but not necessarily) involve *counts*.

✓ (ethnicity of the patients, age??)

✓ Number of tablets/hours

✓ UJ grading system.

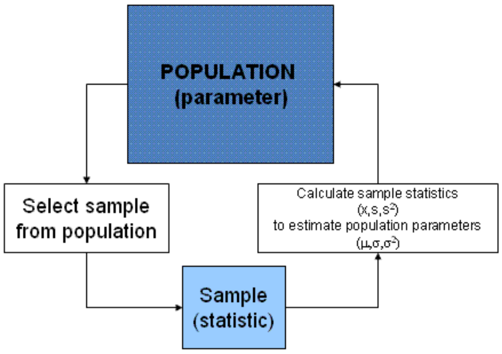
Variable		
UJ grading system (A, A-, B+, B, B-.....)	Quantitative	Discrete
Age (rounded to the highest integer)	Quantitative	Discrete
Nationality of students	Qualitative	Discrete
Height, weight, hardness, Cmax, t max...	Quantitative	Continuous

Samples & Population

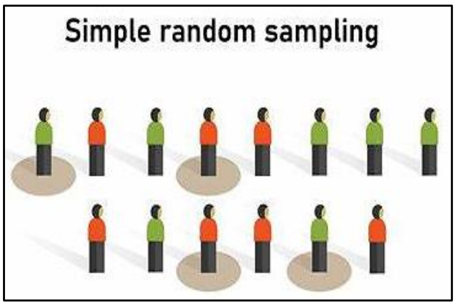
- ***Population N***: It is an entire group, collection or space of objects which we want to characterize. In case population is *too large* to study we need to take a reprehensive sample.
    - ✦ Example:
      If we want to study the bad effects of smoking on ***UJ's student:*** The population is ***all students*** in University of Jordan.

- ***Sample:*** It is a collection of observations on which we measure one or more characteristics. Frequently, we use (small) samples of (large) populations to characterize the properties and affinities within the space of objects in the population of interest.
    - ✦ Example:
      If we want to characterize the US population, we can take a *sample* (poll or survey) and the ***summaries*** that we obtain from the sample (e.g., mean age, race, income, body weight, etc.) may be used to study the properties of the population, in general.

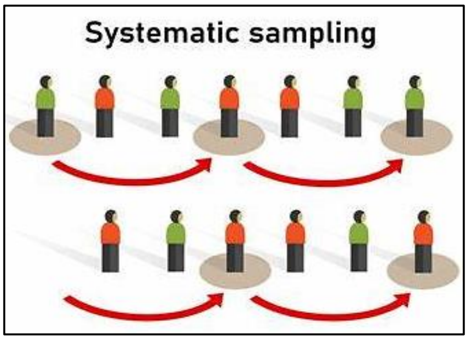
- Descriptive measures that describe a ***Population*** are called ***Parameters***.
- Descriptive measures that describe a ***Sample*** are called ***Statistics.***
- In statistics, we reach a conclusion about a population ***based on*** information contained in a sample that has been drawn from that population.



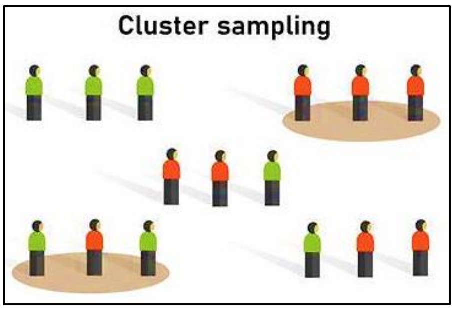
- ***Sampling methods:***
    - *Simple Random Sample* ***(SRS)***
        - ✓ *The simplest type* of scientific samples that may be used for analysis.
        - ✓ If a sample of size ***n*** is drawn from a population of size ***N*** in such a way that every variable in the group N has the same chance of being selected, the sample is called a simple random sample
        - ✓ Each individual in ***n*** is chosen randomly and entirely by chance.



- *Systematic sampling*
    - ✓ It is a process by which every **n**th object is selected.
        - ✦ Example:
            - Consider a mailing list for a survey.
            - The list is too large for us to mail to everyone in this population.
            - Therefore, we select every 6th or 10th name from the list to reduce the size of the mailing while still sampling across the entire list (A-Z).

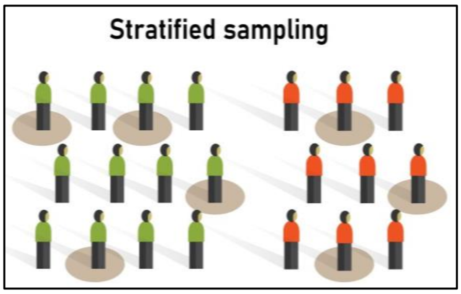


- *Cluster sampling*
  - It is a probability sampling method in which you divide a population into ***clusters***, such as districts or schools, and then randomly select some of these clusters as your sample.



    - Example:
      - Assume that 150 containers of a bulk powder chemical arrive at a pharmaceutical manufacturer and the quality control laboratory needs to sample these for the accuracy of the chemical or lack of contaminants.
      - Rather than sampling each container we randomly selected *10 containers*
      - Then within each container of the ten containers we further extract random samples (from the top, middle bottom) to be assayed.

- *Stratified sampling*
  - Involves random selection within ***predefined groups***.
  - It's a useful method for researchers wanting to determine what aspects of a sample are highly correlated with what's being measured.
  - The population is divided into groups (strata) with similar characteristics and then individuals or objects can be randomly selected from each group *according to its % in the whole population*.



    - Example:
      In a study we may wish to ensure a certain percentage of smokers (**25%**) are represented in both the control and experimental groups in a clinical trial (**n=100** per group). First the volunteers are stratified into smokers and non-smokers. Then, 25 smokers are randomly selected for the experimental group and an additional 25 smokers are randomly selected as controls.

- The simple random sampling, systemic sampling, stratified sampling and cluster sampling ***all called*** ***"Probability sampling"***

Measurement and Measurement Scale

- ***A measurement***: the assignment of numbers to objects or events according to a set of rules.
  - The various measurement scales result from the fact that measurements may be carried out under different set of ***rules:***
    1. The ***nominal*** scale (male, female).
    2. The ***ordinal*** scale (Good-Very Good-Excellent).
    3. The ***interval*** scale (20, 30, 40, 50 C°).
    4. The ***ratio*** scale (20, 30, 40, 50 Kg)

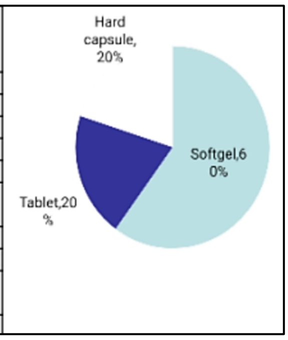
- ***Nominal Scale***

➢ Consists of "naming" or "classifying" observations into various mutually exclusive and collectively exhaustive categories. (Male-female, well–sick, under 65 years of age-65 and over, child–adult, Drug A- drug B, Tablet Capsule)

✓ ***Coded,*** but cannot be ranked as male can be coded as 1 and female as 2 or vice versa (2 for male and 1 for male). (meaning 1 is not lower than 2)

✦ Example 1: 10 subjects answered a question on the preferred dosage form. The data are presented as Pie or column chart.
(Mean and standard deviation *cannot* be calculated)

Subject #	preferred dosage form	Code
1	Softgel	3
2	Softgel	3
3	Softgel	3
4	Tablet	1
5	Softgel	3
6	Hard capsule	2
7	Tablet	1
8	Softgel	3
9	Hard capsule	2
10	Softgel	3



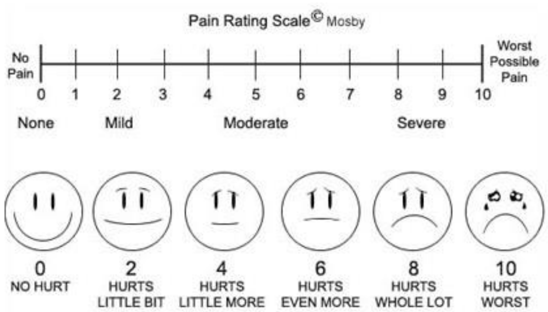
✦ Example 2:
For Pharmacists in a Pharmaceutical company, in which department do you work? administration, plant, or marketing.

- ***Ordinal Scale***

➢ Deals with observations that are not only different from category to category but *can be ranked* according to some criterion.

✦ Examples:

1. Rank in college (freshman, sophomore, junior, senior), size of soda (small, medium, large), the intelligence of children (above average, average, below average).
2. You might ask patients to express the amount of ***pain*** they are feeling on a scale of ***1 to 10***.
   - A score of 7 means more pain than a score of 5, and that is more than a score of 3. ***But*** the difference between the 7 and the 5 may ***not*** be the same as that between 5 and 3. The values simply express an order only.



✓ In each of the previous examples, the members of any one category are considered equal but the members of one category are considered lower, better or smaller than those in another category. The function of numbers assigned to ordinal data is to order or rank the observations from *lowest to highest*

- ***Interval scale***
  - ✓ A scale where the *difference between two values is* ***meaningful*** (not like the ordinal!!) and can be ranked.
  - ✓ In the interval scale, it is not only possible to order measurements but also the *distance* between any
  two measurements is known.
    - ✦ Example:
      - ✓ We know that the difference between T=40 C° and a T=60 C° is equal to the difference between T=60 C° and a T=80 C°
      - ✓ The ability to do this implies the use of a unit distance and a zero point. (The selected *zero point* is not necessarily *a true zero* in that it does not have to indicate a total absence of the quantity being measured).
      - ✓ Good examples of interval scales are the Fahrenheit and Celsius *temperature scales*.
      - ✓ A temperature of ***"zero"*** does not mean that there is no temperature...it is just an arbitrary zero point.

- ***Ratio variable***
  - ➢ Has all the properties of an interval variable and has a *clear definition of a zero point.*
    - ✓ When the variable equals **0.0**, there is **none** of that variable.
  - ➢ Variables like [***height***, tablet ***weight***, enzyme activity, concentration] are ***ratio variables.***
    - ✓ Temperature, expressed in F or C, is not a ratio variable. A temperature of 0.0 on either of those scales does not mean 'no temperature'.
    - ✓ However, temperature in degrees ***Kelvin*** in a ratio variable, as 0.0 degrees Kelvin really does temperature'.
    - ✓ Another counter example is ***pH*** mean number. It is **not** a ratio variable, as pH=0 just means 1 molar of H+. A pH of 0.0 does not mean 'no acidity'.
    - ✓ When working with ratio variables, but not interval variables, you can look at the ratio of two measurements.
    - ✓ A weight of 4 grams is twice a weight of 2 grams, because ***weight is a ratio variable***
    - ✓ A temperature of 100 degrees C is not twice as hot as 50 degrees C, because temperature ***C is not a ratio variable***.
    - ✓ A pH of 3 is *not twice* as acidic as a pH of 6, because ***pH is not a ratio variable.***

THE FOUR LEVELS OF MEASUREMENT:

	Nominal	Ordinal	Interval	Ratio
Categorizes and labels variables	✓	✓	✓	✓
Ranks categories in order		✓	✓	✓
Has known, equal intervals			✓	✓
Has a true or meaningful zero				✓

		Measurement Scales			
		Nominal	Ordinal	Interval	Ratio
Number Meaning		Categories	Order	Equal intervals between characteristic	Equal intervals with true zero point
Arithmetic Operations	Inequality	x	x	x	x
	Ordering / Ranking		x	x	x
	Addition / Subtraction			x	x
	Multiplication / Division				x
Descriptive Statistics	Mode	x	x	x	x
	Median		x	x	x
	Mean			x	x
	Standard Deviation			x	x
Statistical Analysis Techniques Commonly Used	Crosstabs / Chi-Square	x	x		
	Rank Order Correlation		x		
	Analysis of Variance (NP)	x	x		
	Correlation			x	x
	Regression			x	x
	Analysis of Variance			x	x
	Factor Analysis			x	x

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