Pharmaceutical statistics

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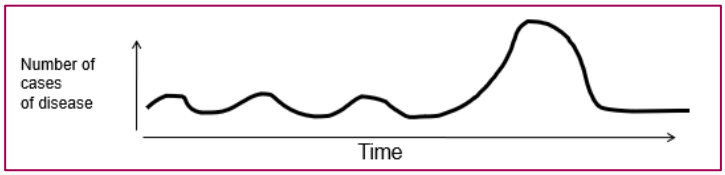
Epidemiology (علم الأوبئة)

- **Epidemiology** is the study of the distribution and determinants (causes or factors) of health-related states or events in specified populations, and the application of this study to control health problems.
  - ★ Example:
    - ✓ What is the incidence of Type II diabetes between 2010-2015 among overweight subjects born in 1970?
    - ✓ What are the possible causes of Type II diabetes in this population?
    - ✓ If we were to change population dietary habits, what improvement in the incidence could we affect?
- **Determinants in epidemiology:**
  - ➢ **Determinant:** any factor, whether event, characteristic, or other definable entity, that brings about a change (negative or positive) in a health condition or other defined characteristic. Epidemiology is also used to search for determinants, which are the causes and other factors that influence the occurrence of disease and other health-related events. Epidemiologists assume that illness does not occur randomly in a population but happens only when the right accumulation of risk factors or determinants exist in an individual.
  - ★ Examples:
    - ✓ Is smoking associated with higher risk of lung cancer.
    - ✓ Is obesity is associated with a higher risk of Type II diabetes.
    - ✓ Is high fiber food is associated with lower risk of colon cancer
- **Endemic:** The habitual presence (or usual occurrence) of a disease within a given geographic area (malaria in a topical region).
- **Epidemic:** The occurrence of an infectious disease clearly in excess of normal expectancy, and generated from a common or propagated source (flu outbreak in winter).
- **Pandemic:** A worldwide epidemic affecting an exceptionally high proportion of the global population (COVID-19).



- **Prevalence vs. Incidence**
  - ➢ Prevalence is the number of existing cases of disease in the population during a defined period.

    Number of Cases Existing in a Given Population at a Single Point in Time / Population at That Time
  - ➢ Incidence is the number of new cases of disease that develop in the population during a defined period.

    Number of New Cases Occurring in a Given Population in a Specified Time Period / Population at Risk in That Time Period.

- **Types of studies:**
  - **Observational studies**
    Observational studies are ones where researchers observe the effect of a risk factor, diagnostic test, treatment or other intervention without trying to change who is or isn't exposed to it.
  - **Experimental studies**
    Experimental studies are ones where researchers introduce an intervention and study the effects. Experimental studies are usually randomized, meaning the subjects are grouped by chance.
  - ★ For example, in **Randomized controlled trial** Eligible people are randomly assigned to one of two or more groups. One group receives an intervention (such as a new drug) while the control group receives nothing or an inactive placebo. The researchers then study what happens to people in each group. Any difference in outcomes can then be linked to the intervention.
  - **Retrospective study:**
    Looks backwards and examines exposures to suspected risk or protection factors in relation to an outcome that is established at the start of the study.
  - **Prospective study:**
    Watches for outcomes, such as the development of a disease, during the study period and relates this to other factors such as suspected risk or protection factor(s). Study usually involves taking a cohort (group) of subjects and watching them over a long period.
  - Basic Measures of Association: In the above studies, we often need to know the relationship between an outcome and certain factors (e.g., age, sex, race, smoking status, etc.). Relative risk & odds ratio are used for this purpose.
- **Case-control studies**
  - **Case-control studies** select subjects based on their disease status. They are usually retrospective study.
  - A group of individuals that are disease positive (the "case" group) is compared with a group of disease negative individuals (the "control" group).
  - The control group should ideally come from the same population that gave rise to the cases. The case-control study looks back through time at potential exposures that both groups (cases and controls) may have encountered.
  - Case control studies are observational because no intervention is attempted, and no attempt is made to alter the course of the disease.
  - A 2×2 table is constructed, displaying exposed cases (A), exposed controls (B), unexposed cases (C) and unexposed controls (D).
  - The exposure **odds** are defined as the **probability** that the exposure probability will occur divided by the unexposure **probability** that the exposure will not occur (unexposed).
    - ✓ Odds = P/(1-P).
    - ✓ For cases = (A/(A + C))/(C/(A + C)) = A/C
    - ✓ Similarly for controls Odds = B/D

Contingency (or 2 x 2) Table

	Cases	Controls	Total
Exposed	a	b	a+b
Unexposed	c	d	c+d
Total	a+c	b+d	a+b+c+d

OR = (a/c) / (b/d)
= (a*d) / (b*c)

  - The statistic generated to measure association is the odds ratio (OR), which is the ratio of the odds of exposure in the cases (A/C) to the odds of exposure in the controls (B/D), (Which is the Odds of exposure in cases / odds of exposure in controls)
  - **OR = (AD/BC).**

★ **Example**

Suppose that an unusual number of patients (19) diagnosed with salmonella were admitted to a hospital on one day, and all patients were from confined geographic area. A sample of 38 non-diseased people as a comparison group (the controls). In this case, the "controls" were non diseased people who were matched to the cases with respect to age, gender, and neighborhood of residence. The case and control groups answered a questioner listing several types of food that may be sources of infection. The results of two types of food are listed:

- ✓ Odds Ratio = (10/9) / (19/19) = 1.1 (close to one). This certainly provides no compelling evidence to suggest an association between the cases and egg consumption.

Exposure	Cases	Controls
Ate eggs	10	19
Did not eat eggs	9	19
Total	19	38

- ✓ Odds Ratio = (18/1) / (7/29) = 75
  This suggests those who drank milk had 75 times the risk of being a case compared to those who did not.

Exposure	Cases	Controls
Drank milk	18	7
Did not drink milk	1	29
Total	19	38

- ✓ **OR of 1** suggests that there is no difference between the groups, or there would be no association between the suggested exposure (fish) and the outcome (being ill)
- ✓ **OR of > 1** suggests that the odds of exposure are positively associated with the adverse outcome compared to the odds of not being exposed
- ✓ **OR of < 1** suggests that the odds of exposure are negatively associated with the adverse outcomes compared to the odds of not being exposed. Potentially, there could be a protective effect.

- **Cohort studies**
  - ➢ Cohort studies select subjects based on their exposure status. The study subjects should be at risk of the outcome under investigation at the beginning of the cohort study; this usually means that they should be disease free when the cohort study starts. The cohort is followed through time to assess their later outcome status.
  - ➢ An example of a cohort study would be the investigation of a cohort of smokers and non-smokers over time to estimate the incidence of lung cancer.
  - ➢ The same 2×2 table is constructed as with the case control study. However, the point estimate generated is the relative risk (RR), which is the probability or incidence of disease for a person in the exposed group, P = A / (A + B) over the probability or incidence of disease for a person in the unexposed group, P = C / (C+D).
  - ➢ Relative Risk = $\frac{\left(\frac{a}{a+b}\right)}{\left(\frac{c}{c+d}\right)}$

	Outcome		
Exposure	Case	Absent	TOTAL
Exposed	**a**	**b**	a+b
Unexposed	**c**	**d**	c+d
TOTAL	a+c	b+d	***a+b+c+d***

- Ratio of the incidence rates between two groups.
- Can only be calculated from prospective studies (cohort studies).

$$RR = \frac{\text{incidence or probability among exposed}}{\text{incidence or probability among non-exposed}}$$

- **Interpretation**

✓ **RR > 1:** Increased risk of outcome among "exposed" group.
✓ **RR < 1:** Decreased risk, or protective effects, among "exposed" group.
✓ **RR = 1:** No association between exposure and outcome.

★ Example:

Smoking and low birth weight

✓ Incidence of LBW among smokers $= \frac{120}{360} = 0.333$

✓ Incidence of LBW among non-smokers $= \frac{60}{640} = 0.0938$

✓ **Relative risk** for having a LBW baby among smokers versus non-smokers $= \frac{0.333}{0.0938} \approx 3.6$

✓ The study suggests, the relative risk of having LBW baby among smoker women is 3.6 times that of non-smoker women.

	Birth Weight		
Smoking status	<2500 g	≥2500 g	TOTAL
Smoker	**120**	**240**	360
Non-smoker	**60**	**580**	640
TOTAL	180	820	***1000***

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