An experimental study

Experimental studies are **interventional'** studies (we intervene in their course) that **verify the validity *of* hypotheses expressed on the basis of the results of analytical study (certain etiological relationship, therapeutic effect, preventive approach, etc.).** Their essence is **intentional influencing of the studied circumstances by the solver**.

Experiment

A direct path to knowledge of regularities, i.e. **causal relationships'**. It examines phenomena in conditions that we ourselves determine or change. It demonstrates that a **change in cause'** also results in a **change in result**. It brings with it the well-known **ethical problem** - its implementation requires ''*informed consent'**. Participants have the right to** *interrupt* the study at any time.

Requirements that must be met in the experimental study:

- *control file*,
- "random selection" of members of the studied and control groups,
- use of "blind trial" etc.,

We can carry out these studies *only after successful laboratory tests* (biological, microbiological, immunological).

Study Types

- **Clinically controlled studies'**,
  - they test the **efficacy** of a certain **preventive or therapeutic factor'** - drug, vaccine, medical procedure on individuals (mostly patients, volunteers),
  - are performed in sets of patients with a **certain disease'**,
  - aim to demonstrate the *beneficial effect of a new drug or medical procedure*:
    1. "determination of the so-called reference population" – represents the basic set (persons affected by the monitored disease),
    2. "determining the experimental set" - we will select from the basic one using the method of random selection,
    3. people from the experimental set are randomly *divided into 2 equal-sized sets* - experimental and control,
    4. to the trial file, *we apply a new drug* and to the control file, *the drug commonly used so far* or *placebo*.
  - ***Blind trial method***
    - it is a method of '*preventing distortion* (bias) of the result of a controlled study, which could occur by the subconscious subjective reaction of people (the subject, the attending physician, the evaluator) as a result of the fact that the participants know the plan of the study and can be subconsciously inclined favorably or unfavorably to the tested factor (drug, therapeutic procedure),
  1. **simple blank**,
     - **eliminates individual bias by the patient'** - the patient does not know which file he was assigned to,
     - is used when a double-blind trial cannot be used for serious reasons,
  2. **double blind'**,
     - used most often,
     - **the patient nor the doctor'** who administers the drug under investigation and reads the results of the therapy, **do not know** who is taking the drug under investigation and who is taking the placebo,
  3. **triple blind'**,
     - the most perfect, **patient, doctor or evaluator don't know** who is taking what,
     - the procedure is such that the investigated substance and the placebo are coded already during production, the code is pasted into an envelope, which is opened only after the end of the study and statistical evaluation.
- **Field Controlled Studies'**:
  - they test the '*effectiveness* of a certain preventive, therapeutic factor (vaccine, preventive measure) on a certain population,
  - these are most often:
    - "Effectiveness trial of new vaccines",
    - "a trial of a new way of applying vaccines",
    - verification of "seroconversion, protective effect",
  - these studies should be preceded by studies with several volunteers, the so-called ***pilot studies'**, in which various doses and methods of administration of the tested vaccine would be preliminarily verified,*
  - The **experimental'** and the **control set'** constitute entire populations,
    - can be numbers 100-10,000 for a file,
    - the control set differs from the experimental set only in **1 monitored character'**, e.g. in the case of vaccine testing, we do not vaccinate the control set at all, or we apply the vaccine used so far and then consider this as the standard during the evaluation,
  - if the controlled field study is successful, we can decide on a **practical application'**,

- even then, of course, we continue with **monitoring**, which is focused on complications or late consequences,
- **advantages'**:
  - *the most objective study*,
  - *possibility of influencing exposure*,
  - *possibility of tracking dynamics*,
  - "the possibility of a relatively precise cause-effect relationship",
- **disadvantages'**:
  - *ethical issues*,
  - *financial problems*,
  - *time and organizational demands*,
- the goal of intervention studies, which deal with the study of mass occurring diseases of non-infectious etiology, is usually to find out whether '*a certain factor is in a causal relationship with some disease*,
- these studies are based on the '*elimination* of this suspected factor in one of the monitored groups,
- known studies:
  - ***EPI Study***:
    - examines the *eating habits* of people,
    - uses the 24-hour recall method,
    - it is an advantage if patients also write down the composition of their diet,
    - retrospective methods always contain the danger of bias.
  - ***IARC study***:
    - examines the occurrence of *colorectal cancer in vegetarians* - it occurs less often, but not zero,
    - is used *triple sentnice try*.
  - ***CARET Study***:
    - in a thousand of *ex-smokers* and *people exposed to asbestos* - the mortality from *lung cancer* increased.
  - ***ATBC study'*** *(alpha tocopherol beta carotene cancer prevention study):*
    - higher mortality from tumors,
    - synthetic "beta carotene" is more of a "risk" factor than a protective one.
  - ***Framingham Study***:
    - the study began in 1948 by creating an original cohort of 5,209 volunteers aged 30 to 62 from Framingham, Massachusetts, who had not yet developed overt symptoms of cardiovascular disease, or who had not yet had a heart attack or cerebrovascular accident.
    - at this time the cohort was joined by:
      - "Offspring Cohort" in 1971,
      - "the Omni Cohort" in 1994,
      - "Third Generation Cohort" in 2002,
      - "New Offspring Spouse Cohort" in 2003,
      - "Second Generation Omni Cohort" in 2003,
    - over time, the development of health status in the Framingham population led to the identification of the main '*risk factors for the occurrence of cardiovascular diseases*, which are:
      - *blood pressure*,
      - level of triglycerides and cholesterol in the blood,
      - age, gender and psychosocial factors,
    - in addition, other physiological conditions, such as dementia, have been and are being investigated,
    - also studying '*relationships between genotype and phenotype* from the point of view of cardiovascular issues,
- a group of so-called natural experiments can also be included in the category of experimental epidemiology:
  - in some situations, it is possible to observe and study the occurrence of a disease in such natural '*conditions* that are very *close* to those conditioned by a planned *controlled study* (artificially created conditions),
  - e.g. monitoring morbidity after the installation of an ash separator or monitoring the occurrence of leukemia in Hiroshima after the explosion of the atomic bomb.

Source

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