

*The steps and principles of
research in clinical surgery*

Learning Objectives

- At the end of this session the learner will be able to describe the The steps and principles of research in clinical surgery.

What is meant by research?

- The systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions.

Basic principles of research

1. Inductive – Collect data and try to find the mechanism -Newton.
2. Deductive –Form a hypothesis and match with observations

The clinical research plan is based directly on inductive Newtonian ideas for proceeding from observation to inference.

Why to do research?

1. To advance knowledge for the good of society.
2. To improve the health of people worldwide
3. To find better ways to treat and prevent disease.

The high quality of medical care we enjoy today is built upon years of effort by physicians, physician-scientists, PhDs, and other medical professionals investigating the causes of and potential treatments for disease.

Types of research in Surgery

- **Basic science research(Fundamental Research)-** to increase understanding of fundamental life processes
- **Clinical research-** important questions of normal function and disease using human subjects.
- **Translational Research** takes a result from basic or fundamental science and studies its applicability in the clinical or human situation.
- **Applied Research** seeks the specific knowledge necessary to improve the treatment of a particular disease.

What is clinical research?

1. Clinical research is the branch of scientific endeavor devoted to the evaluation of patients and the analysis of associated health outcomes.
2. These analyses serve to identify potential areas for change in physician or patient behavior or in clinical processes.
3. The findings will be used to modify clinical practice to achieve better outcomes.

Clinical Research

Clinical research involves interaction with -

1. Patients
2. Diagnostic clinical materials or data
3. Populations

Clinical Research Areas

- Disease mechanisms;
- Translational research
- Clinical knowledge, detection, diagnosis, and natural history of disease
- Therapeutic interventions, including clinical trials
- Prevention and health promotion
- Behavioral research
- Health services research
- Epidemiology
- Community-based and managed care-based research.

Evidence Based Medicine.

- Evidence-based medicine is the foundation on which clinical research is built and is the explicit use of scientific data in decision making for clinical care.

Steps

- Louis Pasteur established the “IMRD” format for reporting scientific information:
 1. Introduction
 2. Methods
 3. Results
 4. Discussion

Steps

1. Background and objectives
2. Literature review
3. Trial design
4. Ethical approval
5. Funding
6. Register in registry.
7. Recruit participants
8. Data collection
9. Analysis
10. Conclusions
11. Discussion
12. Publish

Study Designs

- Randomized controlled trial (RCT):
- Observational studies
 - Retrospective (Data Mining)
 - Prospective
- Interventional studies
- Cohort study
- Case-control study
- Cross-sectional study
- Case series/case report
- Multicenter trials
- Systematic review and meta-analysis

Principals of research

1. Informed consent
2. Safety and ethical considerations
3. Validity and reliability
4. Statistical significance
5. Transparency and openness
6. Conflict of interest
7. Bias
8. Validity
9. Sampling
10. Blinding
11. Randomisation
12. Study protocol
13. Peer review
14. Plagiarism

Bias

- An error which tends to produce results or conclusions that differ systematically from the truth.
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Types of Bias

1. Selection Bias
2. Classification bias, also aka measurement or information bias
3. Confounding bias is a spurious association made between the outcome and a factor that is not itself causally related to the outcome.
4. Lead-time bias
5. Publication bias

Validity

- Internal validity examines whether the study design, conduct, and analysis answer the research questions without bias.
- External validity examines whether the study findings can be generalized to other contexts.

Plagiarism

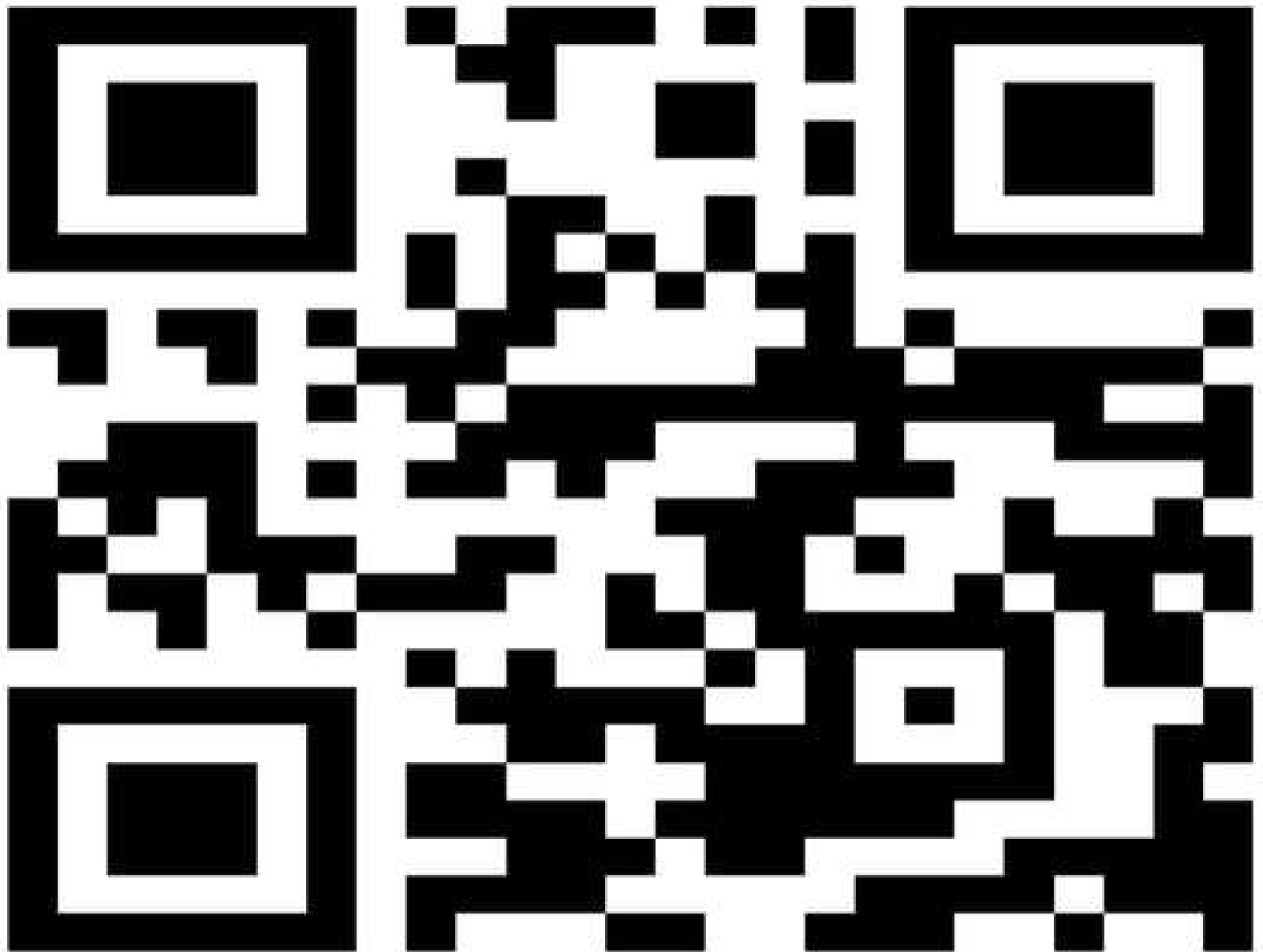
- **Plagiarism** is the fraudulent representation of another person's language, thoughts, ideas, or expressions as one's own original work.
- Not citing (acknowledging) the source is also plagiarism.
- It is a serious ethical offense.
- Punishable.

Types of Plagiarism

- Direct Plagiarism. Direct plagiarism is the word-for-word transcription of a section of someone else's work, without attribution and without quotation marks. ...
- Self Plagiarism. ...
- Mosaic Plagiarism. ...
- Accidental Plagiarism.

Conflict of Interest

- Source of funding.





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