Surgical audit and research

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2023-2024

Learning objectives

- To understand the planning and conduct of surgical audit and research.
- To understand how to write up a project.
- To understand how to review a journal article and determine its value.

Is Clinical Audit A research

Research asks:

Are we singing the right song?

Audit asks:

Are we singing <u>this</u> song right?

HISTORY

- One of first ever clinical audits was undertaken by Florence Nightingale during the Crimean War of 1853-1855.

AUDIT OR RESEARCH?

- Health professionals ***are expected to undertake*** **audit** and **service evaluation** as **part of quality assurance.**
- Audit usually involve **minimal additional risk**, burden or intrusion **for participants.**
- It is ***important*** to determine **at early stage** whether a **project is *audit* or *research.***
- **the differentiation between audit and research by three overarching questions:**

1. Are the **participants** in your study **randomised to different groups?**

2. Does your study protocol demand **changing treatment/care/services** from **accepted standards** for any of the patients/service users involved?

3 .Is your study designed to **produce generalisable** or **transferable** findings?

- ✓ **generalisable'** means the findings can be reliably **extrapolated** from the study to a **broader population of patients**/service users and/or applied to settings or contexts other than those in which they were tested.
- ✓ **'transferable'** means that the findings of a **qualitative study** can be assumed to be **applicable to a similar context** or setting.
- **Most qualitative** studies are **not usually generalisable** but can quite often be considered to be **transferable.**

AUDIT AND SERVICE EVALUATION

- **Clinical audit** is a process used by clinicians who seek to **improve patient care.**
- The process involves **comparing aspects of care** (**structure**, **process** and **outcome**) against **explicit criteria** and **defined standards.**

1. Structure – what is in place

- The people,
- Their training,
- Their knowledge,
- The way they are led,
- The equipment,
- Their organization,
- The way they are paid, etc.

2. Process – what you do

- How referrals are processed,
- What diagnostic tests are done,
- The antibiotics that are used,
- The thromboembolic prevention that is customary,
- The use of intensive care,
- The policy of feeding & mobilization after surgery,
- The discharge policy, etc.

3. Outcome – The Results You Get

- Wound dehiscence rate,
- Readmission rates,
- Mortality,
- Freedom from progression,
- Reduction in symptoms,
- Improvement in quality of life,
- Return to work, etc.

- **There are two main types of audit in common practice**
  - single site/local audits
  - multisite regional, national or international audits.
- **The following steps are essential to establish an audit cycle:**

1. Define the **audit question** in a multidisciplinary team.

2 .Identify the body of evidence and **current standards.**

3 .**Design the audit** to measure performance against agreed standards based on strong evidence.

4. **Measure** over an agreed interval.

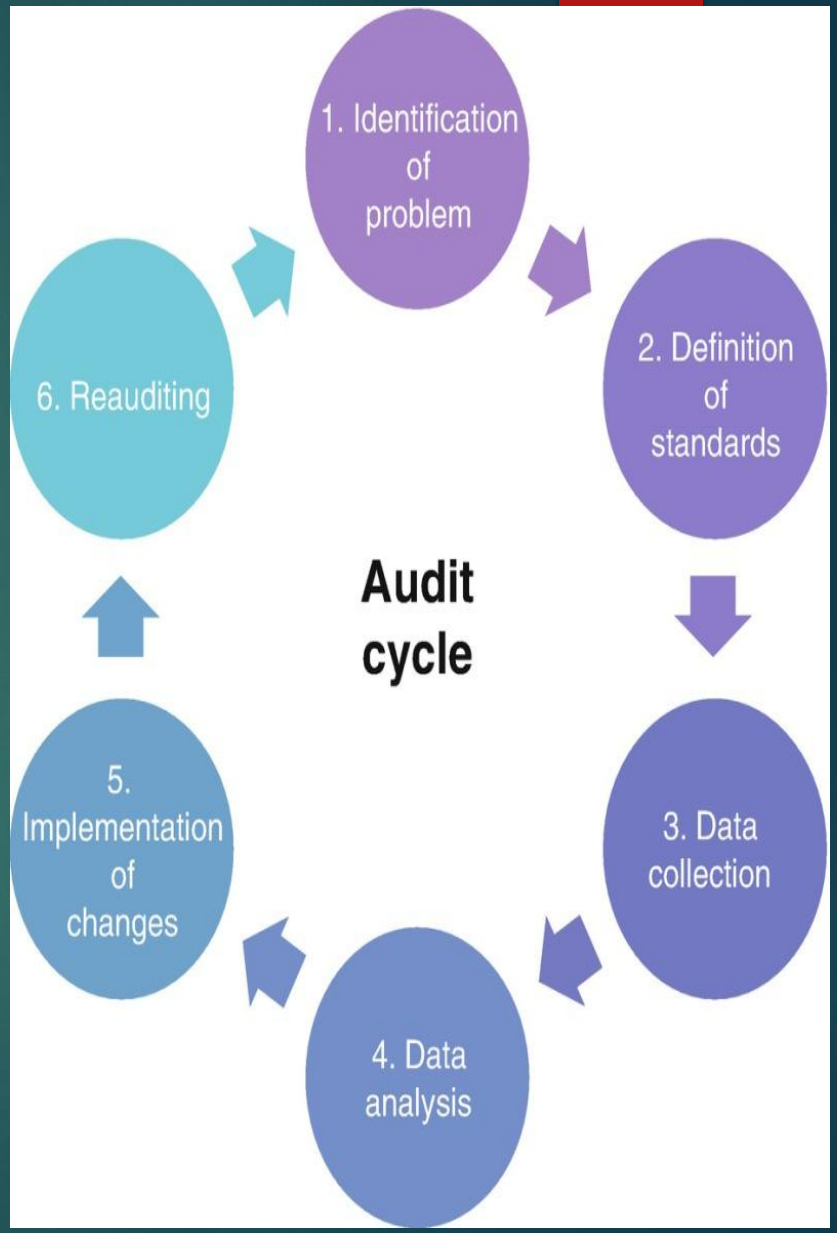
5 .**Analyse** results and compare performance against agreed standards.

6. **Undertake gap analysis:**

(a) if all standards are reached, reaudit after an agreed interval;

(b) if there is a **need for improvement**, identify possible interventions such as training, and agree with the involved groups.

7. **Reaudit.**



- surgeon's own performance is **monitored continuously** and can be **compared** with **a national data** set to ensure compliance **with agreed standards.**
- If care **falls short of the guidance** standard being compared against, **some change in the way** that care is organised should be proposed.
- This change may be required at one of many levels.
  - It might be **an individual** who needs training
  - **surgical equipment** that needs replacing.
  - the change may need to take place **at the team level.**
  - Sometimes, the only appropriate action is change at
    - institutional level (e.g. a new antibiotic policy),
    - regional level (provision of a tertiary referral centre)
    - or, indeed, national level (screening programmes and health education campaigns).

IDENTIFYING A RESEARCH TOPIC

- **Research** is designed to **generate new knowledge** and might involve testing a **new treatment** or regimen.
- Once **an idea** has been formed, or **a question asked**, it needs to be transformed into a **hypothesis.**
- As **ideas are suggested**, it is important to consider whether the **question posed really matters.**
- Spending time **refining the question (hypothesis)** is probably the **most important part** of the process.
- The **first port** of call for information is **the Internet.**
- Current articles about the proposed research should be retrieved; **review articles** and **meta-analyses** can be particularly helpful.

FORMING A TEAM

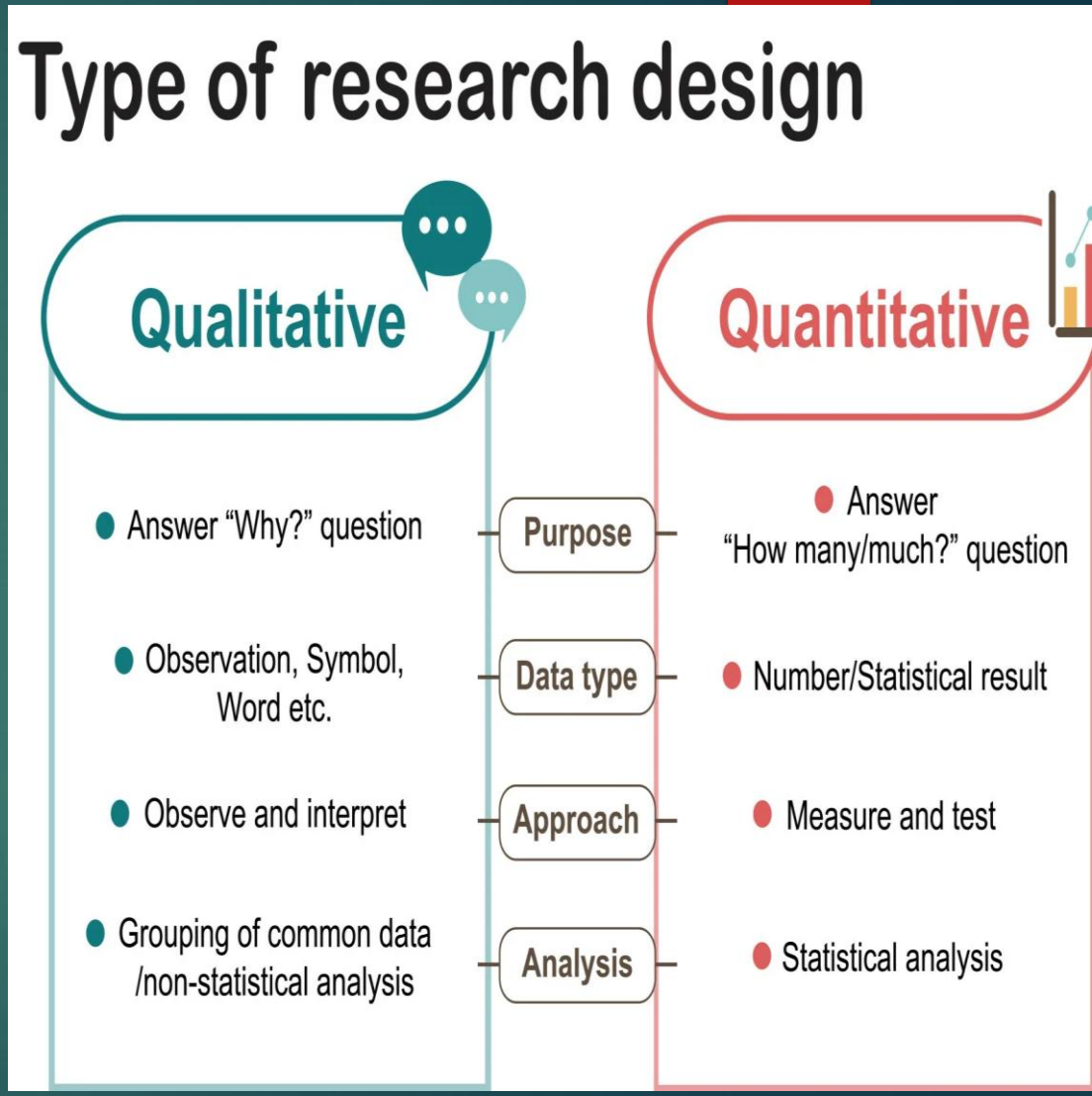
- to create and conduct prospective research projects that **simultaneously collate data** from **across all of the members' units**
- to take advantage of **the rotation of trainees'** postings between units to **ensure project longevity** and thus **enable longer term outcome collection.**
- By achieving a **critical mass of engaged members** in these projects, the collective momentum **ensured completion** even if individuals were unable to personally contribute in a consistent manner because of examinations, family life or busy clinical periods. Such research collaboratives can be most effective in undertaking two key types of study: ***(i) simple randomised controlled trials (RCTs)*** and (***ii) multicentre snapshot audits***
- People can join **at any stage** from **medical student** to **consultant.**
- Anyone interested in surgical research should seek out their local or **national surgical research** collaborative group and get involved.

PROJECT DESIGN

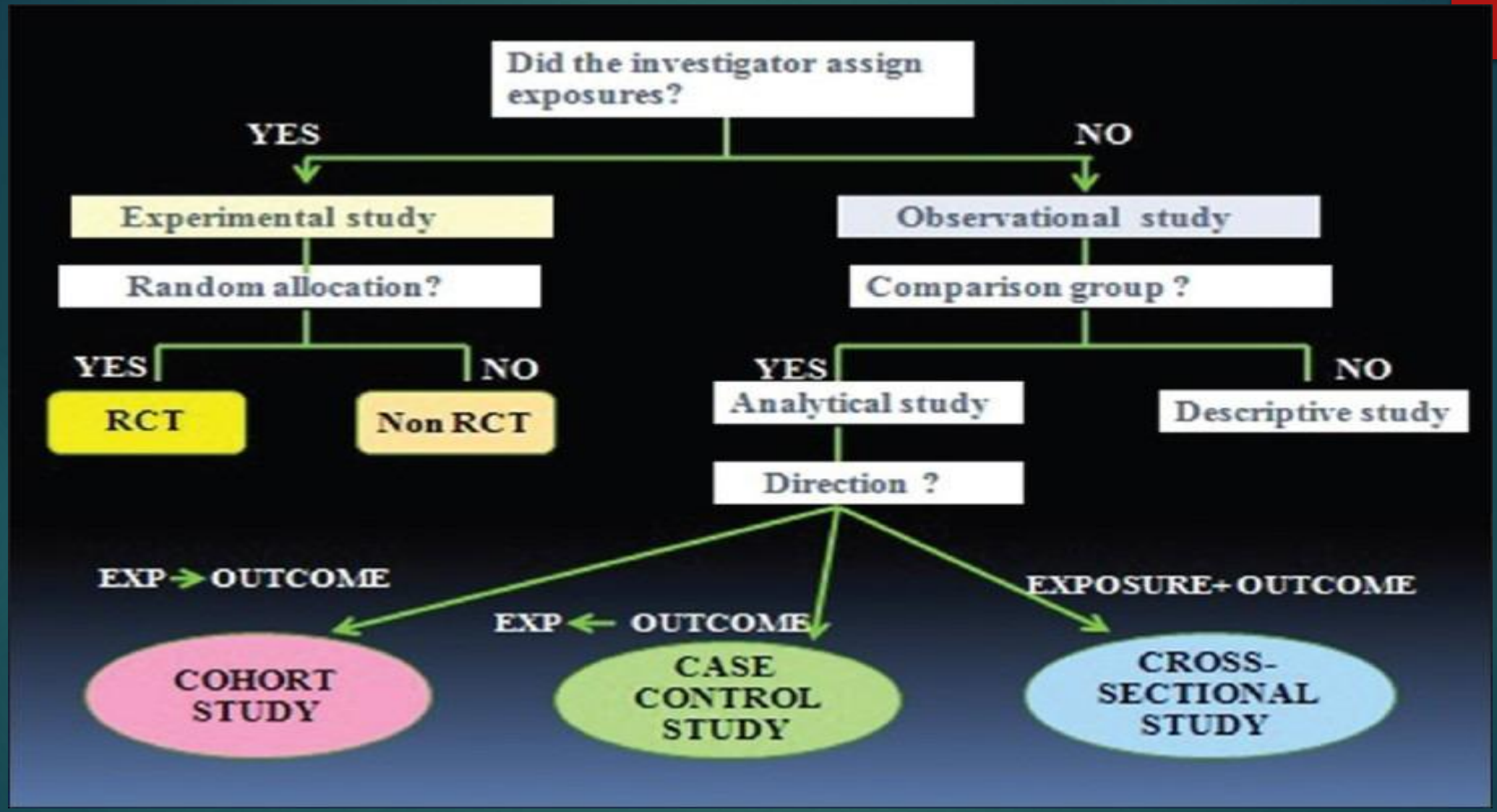
- **Questions to answer before undertaking research**
  - **Why** do the study?
  - Will it **answer** a useful question?
  - Is it **practical?**
  - Can it be **accomplished** in the available time and with the available resources?
  - Will the project **benefit** from collaboration to increase numbers or make best use of high-technology equipment?
  - What **findings** are expected?
  - What are the research **governance requirements?**
  - What are the **ethical issues?**
  - What **impact** could it have?

- Research can be ***qualitative*** or ***quantitative.***
- **Quantitative** research allows **hard facts to speak for themselves.**
  - A medical condition is analysed systematically using hard, objective endpoints such as death or major complications, which should be **clearly defined.**
- **Qualitative** research, data often come from **patient narratives**, and the psychosocial impact of the disease and its treatment are analysed;
  - for example, narratives from patients with **breast cancer.**
  - These kinds of data are often collected using **quality-of-life measurements.**

  A variety of different **quality-of-life questionnaires** exist to **suit several different clinical situations.**
- Much of the best research **is both quantitative and qualitative.**



Type of study	Definition
Observational	Evaluation of condition or treatment in a defined population
	Retrospective: analysis of past events
	Prospective: contemporaneous collection of data
Case–control	Series of patients with a particular disease or condition compared with matched control patients
Cross-sectional	Measurements made on a single occasion, not looking at the whole population but selecting a small similar group and expanding results
Longitudinal	Measurements taken over a period of time, not looking at the whole population but selecting a small similar group and expanding results
Experimental	Two or more treatments are compared. Allocation to treatment groups is under the control of the researcher
Randomised	Two or more randomly allocated treatments
Randomised controlled	Includes a control group with standard treatment


Did the investigator assign exposures?
YES
NO
Experimental study
Observational study
Random allocation?
Comparison group ?
YES
NO
YES
NO
RCT
Non RCT
Analytical study
Descriptive study
Direction ?
EXP → OUTCOME
EXP ← OUTCOME
EXPOSURE+ OUTCOME
COHORT STUDY
CASE CONTROL STUDY
CROSS-SECTIONAL STUDY

Sample size

- **Calculating the number** of patients required to perform a satisfactory investigation is **an important prerequisite to any study.**
- An **incorrect sample size** is probably the most frequent reason for research being invalid.
  - ***Type I error. Benefit is perceived*** when **really there is none (false positive).**
  - ***Type II error. Benefit is missed*** when **it was there to be found (false negative).**
- Calculating the number of patients required in the study can overcome this bias.
- **Unfortunately**, it often reveals that **a larger number of patients** is needed for the study than can possibly be obtained from available local resources.
- This usually means expanding enrolment by running a **multicentre study**
- *A longer time* from trial entry to primary outcome assessment will result in an **increased attrition rate of participants.**

- The following is an example calculation for a study to recruit patients into two groups. In order to calculate a sample size, it is now common practice to set the **level of power for the study at 90%** with **a 5% significance level.** This means that, if there is a difference between study groups, there is a 90% chance of detecting it.
- The formula below uses the results of a reduction in event rate from 30% to 20% (e.g. a new treatment expected to reduce the complication rate such as wound infection from 30% = r to 20% = s).

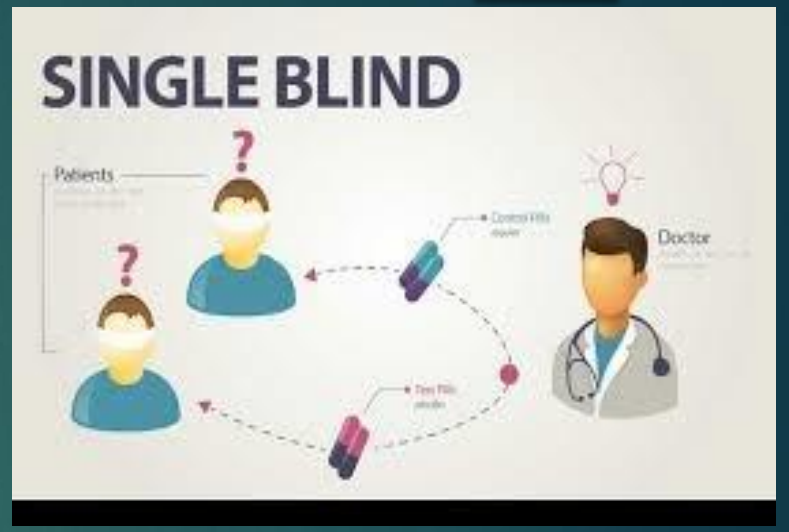
$$9 \times \frac{[r(100 - r) + s(100 - s)]}{(r - s)^2}$$

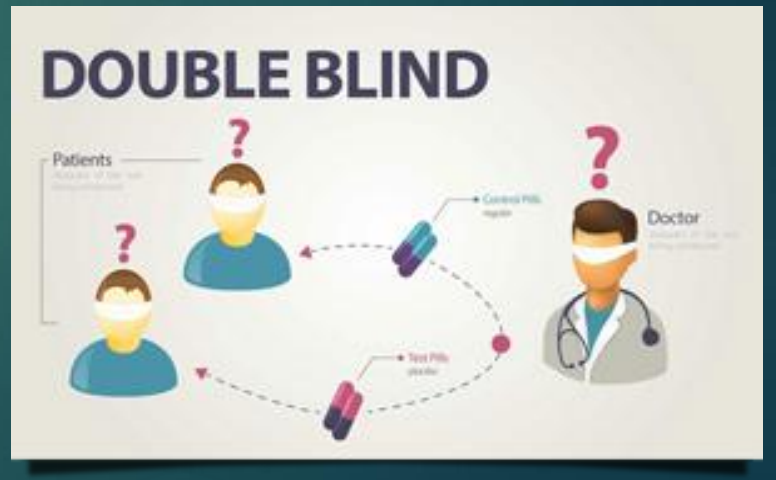
$$\text{e.g. } 9 \times \frac{[30(100 - 30) + 20(100 - 20)]}{(30 - 20)^2}$$

$$= 333 \text{ needed in each group}$$

Eliminating bias

- One way to eliminate any bias inherent in the data collection is to have **observers** or **recorders** who **do not know** which treatment has been used ***(blinded observer).***
- It might also be possible to ensure that the **patient is unaware** of the treatment allocation ***(single blind).***
- In the best randomised studies, **neither patient *nor researcher*** is aware of which therapy has been used until after the study has finished ***(double blind).***
- Randomised **trials are essential** for testing new drugs. In practice, however, in some surgical trials, randomisation may **not be possible or ethical.**





Study protocol

- Now that the ***research question has been decided,***
- it has been checked that ***sufficient patients should be available*** to enrol into the study,
- At this stage, **a study protocol** should be constructed to **define the research plan**

,It should contain :

- ✓ the **background** of the proposed study,
- ✓ the **aims and objectives,**
- ✓ a **clear methodology,**

  definitions of **population** and sample sizes

  Methods of proposed analysis.

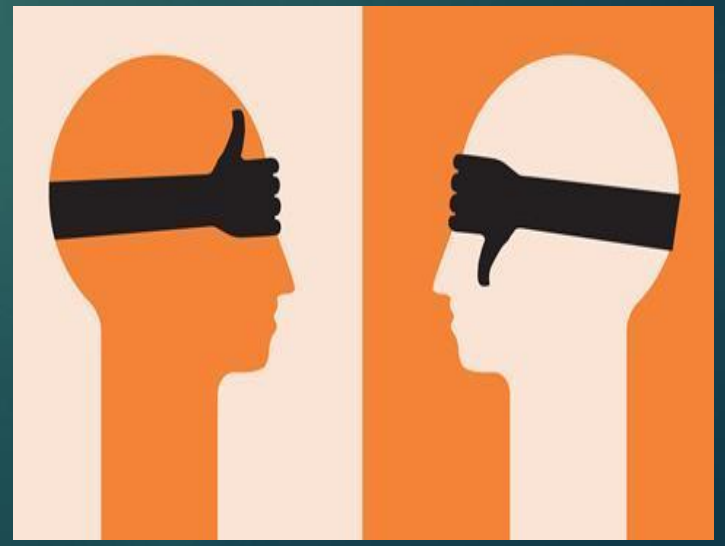
  the patient numbers, **inclusion** and criteria

  the timescale for the work

It is helpful to *imagine the paper* that will be written about the study before the study is performed. This may **prevent errors** in data collection.

Peer review

- Once the protocol is finalised, **formal peer review** is needed.
- In the UK, evidence of peer review will be needed **before submitting** an application to a research ethics committee
- **Many funders of research** will undertake their own independent peer review.
- There is usually **feedback from this process** that can provide *valuable advice about the study.*



Ethics

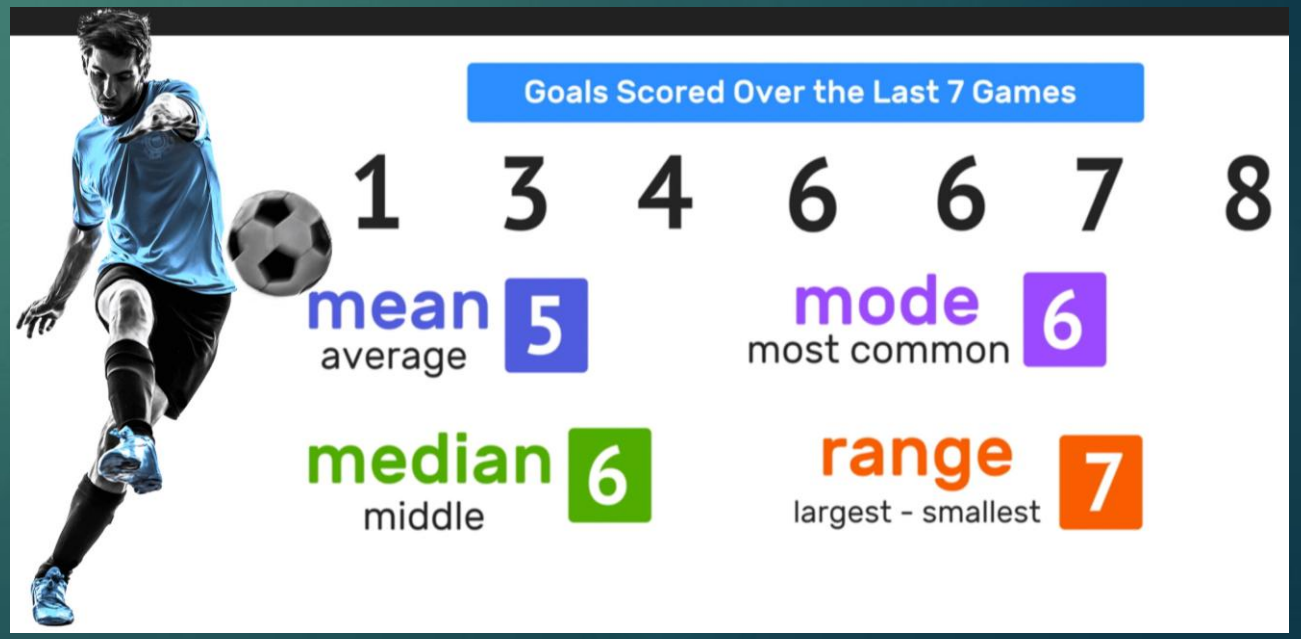
- In the first instance**, common sense** is the best guide to whether or not a study is **ethical.**
- Universities have developed **their own ethical review** infrastructure and this will be institute specific and location specific.
- **Ethics committee** forms may seem *long* and *detailed*, but it is important that these are **filled** in correctly as this helps to prepare the investigators for **all practical aspects of the project.**

STATISTICAL ANALYSIS

- Both ***audit*** and ***research*** commonly **require statistical analysis.**
- Many surgeons find the statistical analysis of a project the most difficult part.
- if in any doubt, **a statistician** will be pleased to give assistance. Statisticians *should be consulted before research or audit has been conducted* rather than being presented with the data at the end; they often give helpful advice over study design and can be an important part of the project team.

- The following terms are frequently used when summarising statistical data:

- **Mean:** the result of dividing the *total by the number of observations (the average).*
- **Median:** the *middle value with equal numbers of observations above and below* – used for numerical or ranked data.
- **Mode:** the value *with the highest frequency* observed – used for nominal data collection.
- **Range:** the *largest to the smallest* value.

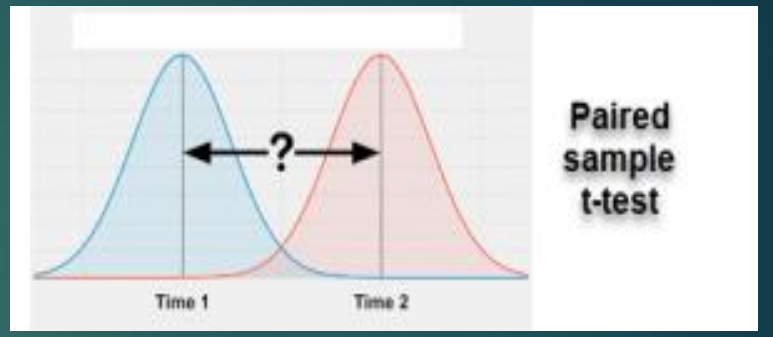


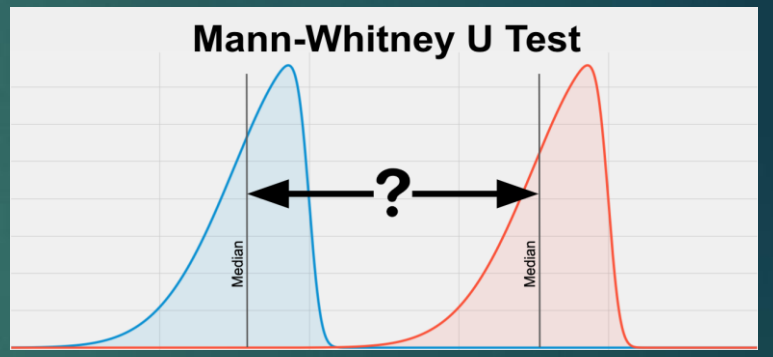
- **The most important decision** for analysis is whether the distribution of the data is normal **(i.e. parametric or non-parametric).**
- **Normally, distributed data** have a symmetrical bell shaped curve, and the **mean, median and mode** all lie at the same value.
- The type of data collected determines which statistical test should be used.

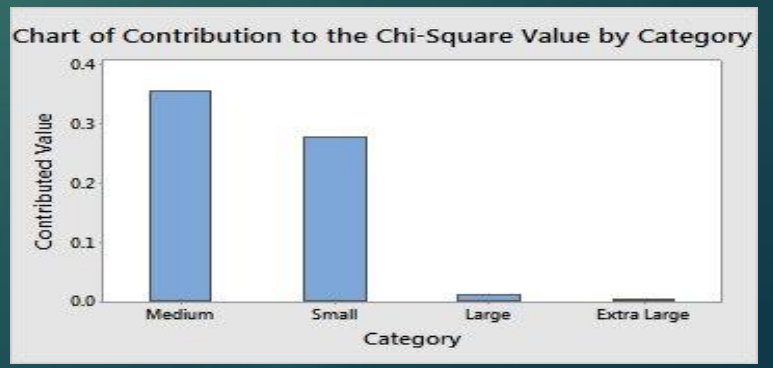
1 .Numerical and normally distributed (e.g. blood pressure) –use an unpaired **t-test to compare two groups** or a paired t-test to assess whether a variable has changed between two time points.

2. Numerical but not normally distributed (e.g. tumour size)– use a Mann–Whitney **U-test** to compare two groups or a Wilcoxon signed rank test to assess whether a variable has increased/stayed the same/decreased between two time points.

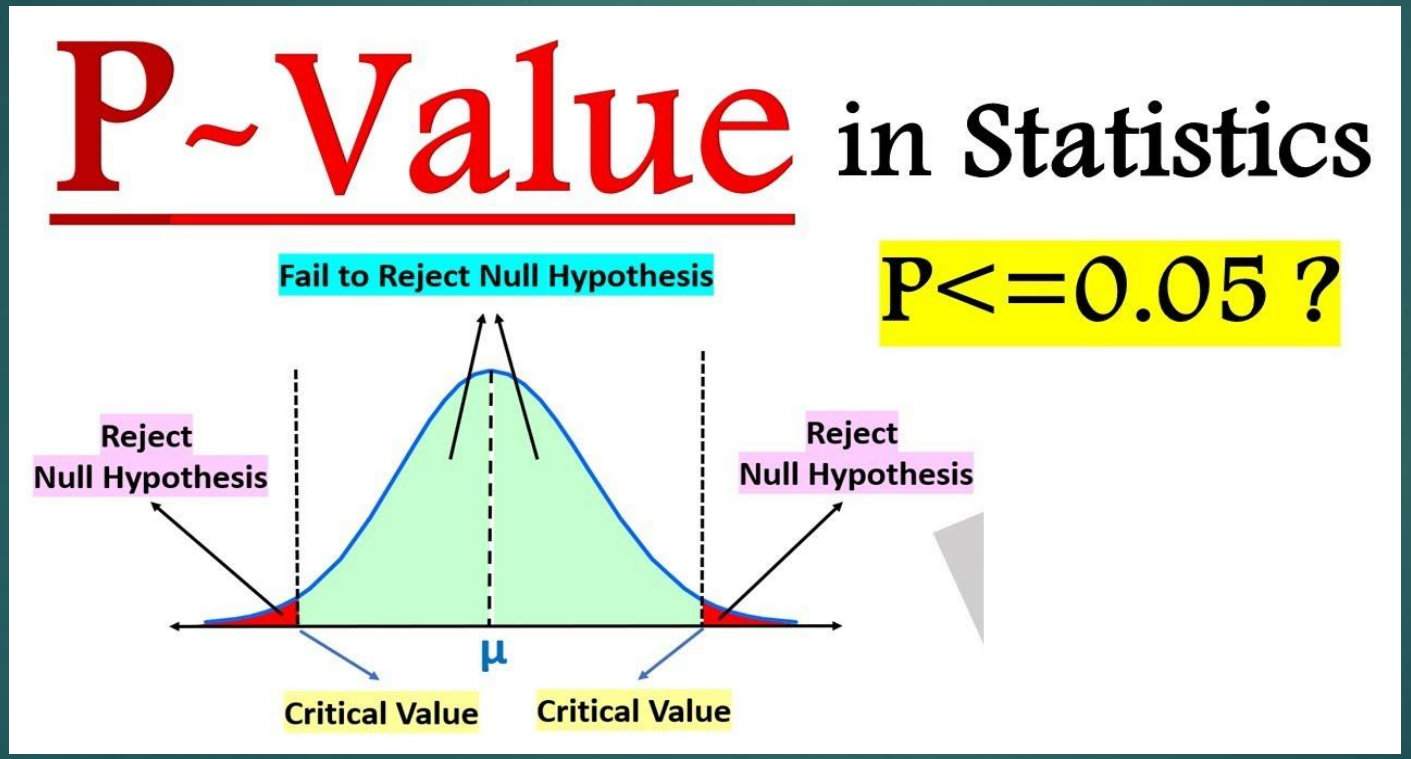
3 .Categorical (e.g. admitted or not admitted to an intensive care unit) – a **chi-squared** test can be used to compare two groups.







- **Scientists usually employ probability (P-values)** to describe statistical chance. ***A P-value <0.05*** is commonly taken to imply a true difference.



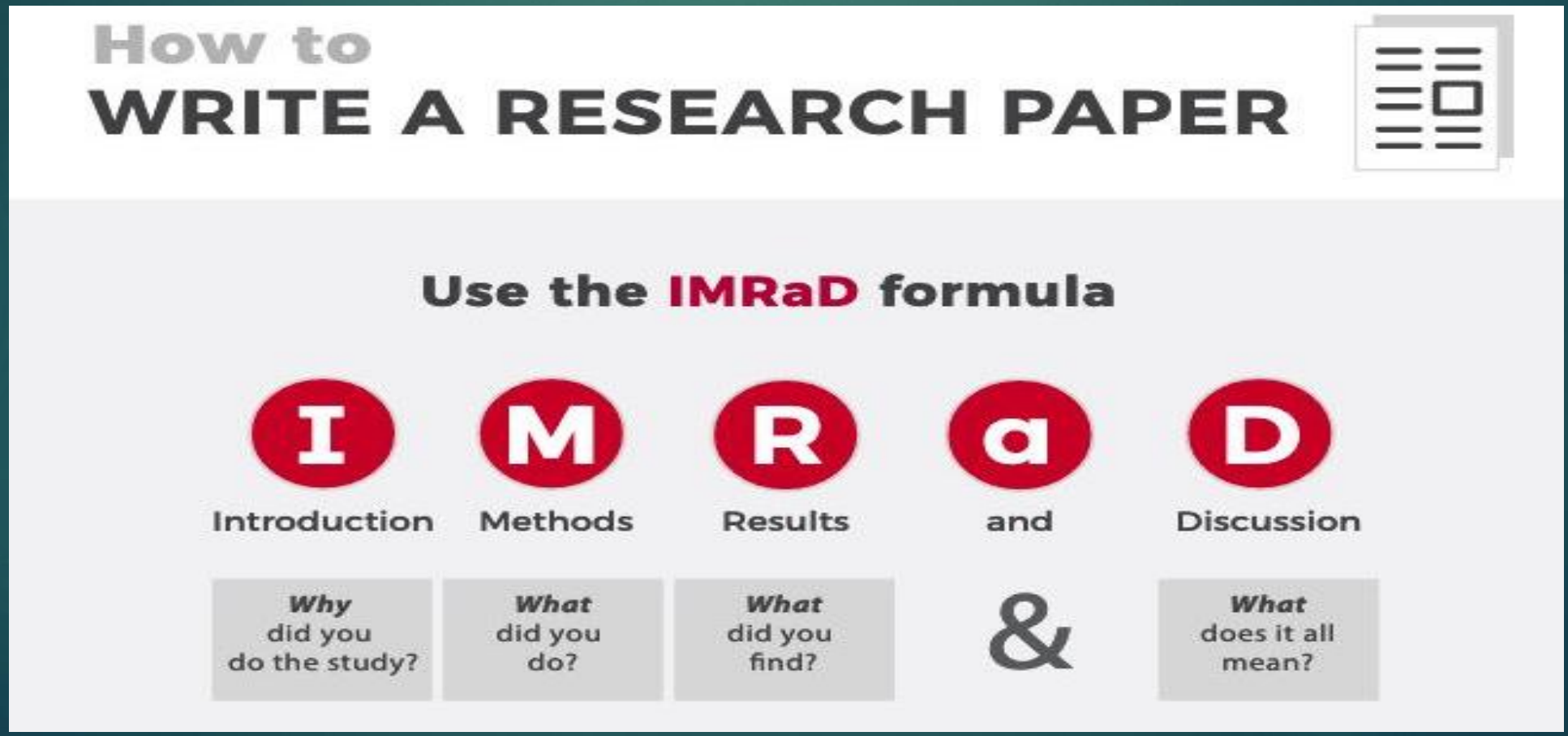
Computer software packages available

- **Statistical computer packages** offer a **quick way of analysing** descriptive statistics such as mean, median and range,
- As well as the most commonly used statistical tests such as the chi-squared test.
- ***Various packages are available*** commercially and are useful tools in data analysis.

PRESENTING AND PUBLISHING AN ARTICLE

- There is **no point** in conducting a ***research*** or ***audit*** project and then leaving the results ***unreported.***
- Even when results **are negative**, they are **worth distributing;**
- **no project if properly conducted is worthless.**
- **Under-reporting of negative outcomes** causes a **systematic bias** in the literature ***in favour of positive trials.***
- Most surgeons publish research in **peer-reviewed journals.**
- The work that **is submitted** is **checked anonymously by other surgeons** before publication.
- It is usually **free to publish in surgical journals** since the *cost of refereeing and editing is borne by the journal subscriber.*
- A second model of publication is becoming more prevalent: ***open access***, in which the **author pays.** This ensures that **all research is visible to anyone**, by pushing the costs of the editorial process onto the study budget.

- ✓ **Convention dictates that articles are submitted** in **IMRAD** form: **introduction**, **methods**, **results** and **discussion.**



- ***Introduction.*** This should always **be short**. A *brief background* of the study should be presented and then the **aims of the trial or audit outlined.**

- ***Methods.*** The methodology and study design **should be given in detail.** It is important *to identify potential biases*. ***New techniques*** or i*nvestigations* should be detailed in full; **if they are common practice or have been described elsewhere**, this should be ***referenced instead of described.***

- ***Results.*** Results are almost always **best shown diagrammatically** using ***tables*** and ***figures.*** Results shown in the form of a diagram ***need not then be duplicated in the text.***

- ***Discussion.***
  - It is important ***not to repeat the introduction*** or reiterate the ***results in this section***.
  - The study should be interpreted intelligently and any suggestions for future studies or changes in management should be made.
  - Recently, a standard format for the discussion section has been promoted, and journals such as the BMJ are keen that authors use it.
- ***References.*** This section should include ***all relevant papers*** recording previous studies on the subject in question. The reference section does not usually have to be exhaustive, but should include **up-to-date articles**. Remember to present the references in the **style of the journal of submission.**

EVIDENCE-BASED SURGERY

- Surgical practice has been considered an art: ask 50 surgeons

how to manage a patient and you will probably **get 50 different answers.**

- There is so much clinical information available that no surgeon can know it all.
- Evidence-based surgery **is a move to find the best ways of managing patients** using **clinical evidence from collected studies.**
- As evidence accumulates, it is expected that this ***will gradually smooth out the differences between clinicians*** as the best way of managing patients becomes more obvious.
- ***Collecting published evidence*** together and analysing it often requires reviews of multiple randomised trials. These **meta-analyses** involve complex statistical analyses designed to interpret multiple findings and synthesise the results of multiple studies.

Difference between research and audit:

	Research	Audit
Purpose	Generalisable new knowledge	Inform delivery of best care
Question	Test hypothesis (quant), explore themes (qual)	Does it reach a pre-determined standard?
Objective	Specific research objectives	To measure service against accepted / defined standard
Interventions	Novel use or application	Already in use
Data additional to usual care	Yes, including invasive tests	Can include questionnaire / interview
Allocation to intervention	Yes, usually	No
Randomisation	Maybe	No

Reference:

- BAILEY & LOVE’S SHORT PRACTICE OF SURGERY 28TH EDITION TEXT BOOK


Any Questions?