

# SCIENTIFIC WRITING

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# Research Output

- Three different research output are expected from research proposals:
  - 1- Paper
  - 2- Patent
  - 3- Change

# Why “Scientific Writing”?

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- The purpose of scientific writing is to convey ideas and facts about scientific work.
- Scientists understand and criticize each other's work through their articles.
- Thus, scientific writing should be intelligible to readers at the first reading.

# Audience

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- ⑩ **Know your audience and write for that specific audience.**
- ⑩ Scientific and technical writing is never a 'general purpose', but written for a specific audience, i.e. the community who read a particular journal or study a particular subject.
- ⑩ You must adopt the style and level of writing that is appropriate for your audience.

# Types of Medical articles

- Original Article
- Review Article
- Case Reports
- Editorial
- Short Communication (short papers)
- Letter to Editor
- Personal Views

# Letter

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- Stick to the point
- State the problem, issue or hypothesis
- Give the context
- Outline your comment, solution, viewpoint
- Give a strong conclusion
- Note limitations

# Editorial

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- Write for your readership (broad?)
- Be controversial and thought provoking
- Being subtle is often more powerful

# Short communication

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- Increasingly common
- Concise introduction
- Present data and discuss it shortly
- Only a few tables or figures
- Number of words limitations

# Case Reports

- Medical history of a single patient in a story form.
- Lots of information given which may not be seen in a trial or a survey.
- Often written and published fast compared to studies
- e.g. Thalidomide

# Case report

- Clinical conditions not described before
- Unusual and unreported presentations of known clinical conditions
- Unexpected beneficial responses to a treatment
- Previously unreported adverse reactions to a treatment
- Errors in diagnosis as a result of use of incorrect tests or presentation with unusual symptoms
- New uses of a diagnostic tool or use of novel diagnostic tools
- Phenotypes associated with a newly found gene

# Is your paper a paper, a brief or a research letter?

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- Easier to get letters & briefs accepted .
- They make you indexed easier !
- Decide whether you should submit it as a brief or letter firstly.

# The Hierarchy of Evidence

1. Systematic reviews & meta-analyses
2. Randomised controlled trials
3. Cohort studies
4. Case-control studies
5. Cross sectional surveys
6. Case reports
7. Expert opinion
8. Anecdotal

# The traditional IMRaD

- Introduction
- Methods
- Results
- Discussion

# Main Components of an Article

- **I**ntroduction: **W**hy did you start?
- **M**ethods: **W**hat did you do?
- **R**esults: **W**hat did you find?
- **D**iscussion: **W**hat does it all mean?

# A full paper may contain:

- Title
- Authors and Affiliation
- Abstract
- Introduction
- Methods
- Results
- Discussion
- Acknowledgments (optional)
- References

# Initial steps

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- 1-Understand the type of manuscript you are writing.
- 2-Re-evaluate your project.
- 3-Plan the sections and subsections you need.
- 4-Match your content to your readers' knowledge.
- 5-Keep information specific rather than general.
- 6-Write in plain language. Keep your sentences short.
- 7-Use tables, diagrams, flowcharts and graphs.

# Introduction

# Introduction

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- Before you begin, answer the basic questions:
  - What do I have to say?
  - Is it worth saying?
  - What is the right format?
  - Who is the audience?
  - What is the right journal?

# Introduction

- General, concise description of problem
  - ▣ background to the work
  - ▣ previous research
- Where that work is deficient
  - ▣ how your research will be better
- State the hypothesis
- About 3 to 4 paragraphs

First

- What we know

Then

- What we don't know

Finally

- What we are going to do

# Introduction

- **Why** is this study of scientific interest and **what** is your objective?
  - discusses the results and conclusions of **previously published studies**, to help explain why the current study is of scientific interest.
- The Introduction is organized to move **from general information to specific information**.
- The background must be summarized succinctly, but it should not be itemized.
- Limit the introduction to studies that relate directly to the present study. **Emphasize your specific contribution** to the topic.
- The **last sentences of the introduction should be a statement of objectives and a statement of hypotheses**. This will be a good **transition to the next section**, Methods, in which you will explain how you proceeded to meet your objectives and test your hypotheses.

# Introduction

1. Existing state of knowledge
2. Gaps in knowledge which research will fill.
3. State what you intend to do & the purpose of article
4. Give pertinent references
5. Summarize the rationale for study or observation
6. Define specialized terms or abbreviations you want to use

# Inverted pyramid

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- The structure should funnel down from a broad perspective to a specific aim

Liver disease has an increasingly high burden

Non alcoholic steatohepatitis...

Follow up of NASH

Fibroscan ...

# Introduction

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- Don't make it a review article
- Don not include methods, results and discussion
- Don't put down every all previous studies & their data gaps
- Don't explain pathophysiology irrelevant to your study

# Introduction

- Tell why you have undertaken the study
- Clarify what your work adds
- Follow the best advice
- Keep it short
- Make sure you are aware of earlier studies
- Tell about importance of your study
- Don't baffle your readers
- Give the study design
- Think about using journalistic tricks

# To write an effective introduction you must:

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- Know your audience
- Keep it short
- Tell readers why you have done the study
- Explain why it is important
- Convince readers that it is better than others
- Try to hook them!

# How to Cite Sources in the Introduction

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- Cite sources in the introduction section of your paper as evidence of the claims you are making.
- Cite the sources in the text so that the reader can find the full reference in the literature, yet the flow of the reading is not badly interrupted.

# Method

# method

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- Allows reader to judge the quality of the work
- Identifies weaknesses
- Allows repetition of the study
- State the study design & specifications

# method

- WWWWWH (who, what, where, why, when & how?)
- Define variables
- Patient/Participants inclusion
- Dates
- Randomisation/Placebo/Blindness
- Ethics/consent
- Treatments
- Outcomes and endpoints
- Statistical methods & power

# Method

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- This section provides all the methodological details necessary for another scientist to duplicate your work
- It should be a narrative of the steps you took in your experiment or study, not a list of instructions such as you might find in a laboratory manual!

# Check-list for Methods

- Study design
- Clear definition of the participants
- Inclusion/exclusion criteria
- logical & chronological order
- Measurements
- Sample size
- statistical analyses
- New techniques validation

**Could the reader reproduce your study from the details provided?**

# Patient / Animals / Specimens

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- Numbers
- How are they grouped
- Criteria
- Informed consent obtained

# Method ...

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- Reason for selecting the design of the study.
- Statistical methods used for analysis
- If standard techniques is used, give appropriate reference, any modifications should be clearly explained
- If new techniques is used, give validity and reliability measures

# If applicable ...

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- Ethical approval
- Questionnaires
- Interventions
- Clinical assessments
- Proper references

# Questionnaires

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- Development
- Validity
- reliability
- The mode of administration:
  - self-administered
  - telephone-administered
  - interviewer-administered

# In Clinical Trials

- Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).
- Method used to implement the random allocation sequence (e.g., numbered containers or central telephone),
- Concealment
  - Who generated the allocation sequence,
  - who enrolled participants
  - who assigned participants to their groups.

# blinding

- Participants
  - those administering the interventions
  - those assessing the outcomes
  - Those analyzing the findings
- 
- If done, how the success of blinding was evaluated.

Result

# Result

- This section presents the results of the experiment but does not attempt to interpret their meaning.
- As with the Methods section, the trick to writing a good Results section is knowing what information to include or exclude.
- You will not present the raw data that you collected, but rather you will summarize the data with text, tables and/or figures.
- Use the text of the paper to state the results of your study, then refer the reader to a table or figure where they can see the data for themselves.

# Results

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- Describe the **population**
- Start with **positive** findings
- Establish how **comparable** your groups were
- Use a mixture of text, tables and figures
- Mention units of measurement
- Mention what numbers, brackets, etc. refer to
- Bring the P values

# Results

- Provide only enough **interpretation** to lead the reader from one experiment to the other
  - ▣ Avoid lengthy analysis and comparison to the work of others
- No need to follow **chronology of study**, provide a **logical progression** and tell a story
- It is not necessary to describe every step of your statistical analyses.

# Results

1. Start with **positive** findings.
2. **Do not compare** the present data with previously published results.
3. Write the text of the Results section **concisely** and **objectively**.
4. The **passive voice** will likely dominate here, but use the active voice as much as possible

# Tables and Figures

- Consider using a table to present **large amounts** of data/results.
- Refer to all tables in text.
- Use **figures** to graphically represent *significant* results.
- Use the **“Stand alone”** tables
- Make sure totals add to **100%**
- **Do not repeat** the Tables and Figures in text
- Summarize, describe, ...

# Tables and Figures ...

- Each Table or Figure must include a brief description of the results being presented and other necessary information in a legend.
- Table legends go above the Table; tables are read from top to bottom.
- Figure legends go below the figure; figures are usually viewed from bottom to top
- Tables generally should report summary-level data, such as means  $\pm$  standard deviations, rather than your data.
- You must refer in the text to each figure or table in your paper.

# Selecting a table or a graph

- It is best to present the data in a table unless there is visual information that can be gained by using a figure.( a line graph for a regression analysis)
- Each table and figure has several lines of text in the caption that explain the information that is being presented; this is, they are made to stand alone.
- Tables and Figures are assigned numbers separately and in the sequence that you will refer to them from the text.
- Only use a figure (graph) when the data lend themselves to a good visual representation. Avoid using figures that show too many variables or trends at once.

**Table 4** Univariate analysis of risk factors for retinopathy of prematurity

Potential risk factor	Odds ratio (95% CI)	p Value
Oxygen therapy	4.648 (2.090 to 10.335)	<0.001
Blood transfusion	2.722 (2.030 to 3.651)	<0.001
Intraventricular haemorrhage	1.382 (0.846 to 2.258)	0.198
Phototherapy	0.794 (0.561 to 1.124)	0.206
Gender (female to male)	1.082 (0.827 to 1.416)	0.584
Multiple gestation	0.974 (0.735 to 1.290)	0.886
Gestational age*	0.641 (0.598 to 0.686)	<0.001
Birth weight†	0.822 (0.790 to 0.854)	<0.001

\*Per week.

†Per 100 g.

# Figures

- Used when we want to distinguish a result & make it prominent into readers view
- Figures are visual presentations of results, including graphs, diagrams, photos, drawings, schematics, maps, etc.
- Graphs are the most common type of figure.
- Graphs show trends or patterns of relationship.

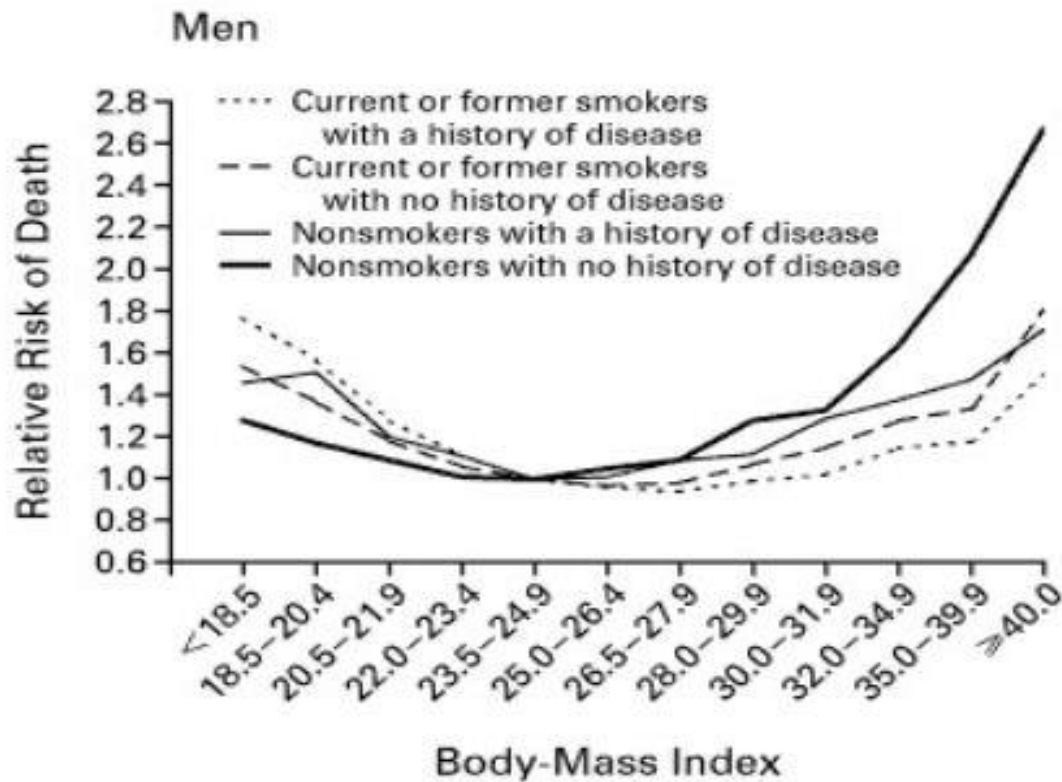
# Figures

- Avoid clutter(too many numbers & symbols)
- Should provide a clear statistical message
- Vertical (“Y”) axis: outcome/dependent variable
- Horizontal (“X”) axis: exposure/independent variable
- Name & define each axis and give the measurement unit of each axis

# graphs

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- Line: trends in time
- Bar: comparisons
- Pie: share of total
- Histogram: frequency
- Scatter: associations



**Figure 1. Multivariate Relative Risk of Death from All Causes among Men and Women According to Body-Mass Index, Smoking Status, and Disease Status.**

The four subgroups are mutually exclusive. Nonsmokers had never smoked. The reference category was made up of subjects with a body-mass index of 23.5 to 24.9.

# Something to avoid !

- ❑ Do not present the same data in both a Table and
- ❑ Do not report raw data values when they can be summarized as means, percents, etc.
- ❑ Avoid 3D graphs and color themes that can not be recognized in grayscale
- ❑ Avoid using figures that show too many variables or trends at once.
- ❑ Avoid using fancy borders, shading, and multiple grids
- ❑ Generally, scientific tables have few horizontal rules and no vertical rules

# Reporting statistics

- Provide numbers as well as percents when sample size is limited
- No need to sample size or statistical test formula
- Present any statistics as well as the P value
- Mention P value, degree of freedom, etc.
- Significant or not, mention the p value (Two decimal points)
- Describe symbols
- Round the statistics

# Remember

- Be consistent in the use of units in your reporting
- never use a figure to describe the baseline characteristics.
- Report comparability of the study groups
  - ▣ unevenly distributed confounders may cause an important bias.
- Generalizability of your results can be evaluated in the method section

# Baseline characteristics

Depend on the type of your variables use:

number and percentage

the mean and its standard deviation

the median and its inter-quartile range

No SE,

No 95% CI

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number and percentage

the mean and its standard deviation

the median and its inter-quartile range

No SE,

No 95% CI

# Check list for Results

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- Baseline data provided?
- Primary and other endpoints clear and complete?
- Does the text complement figures and tables?
- Are measures of uncertainty mentioned?

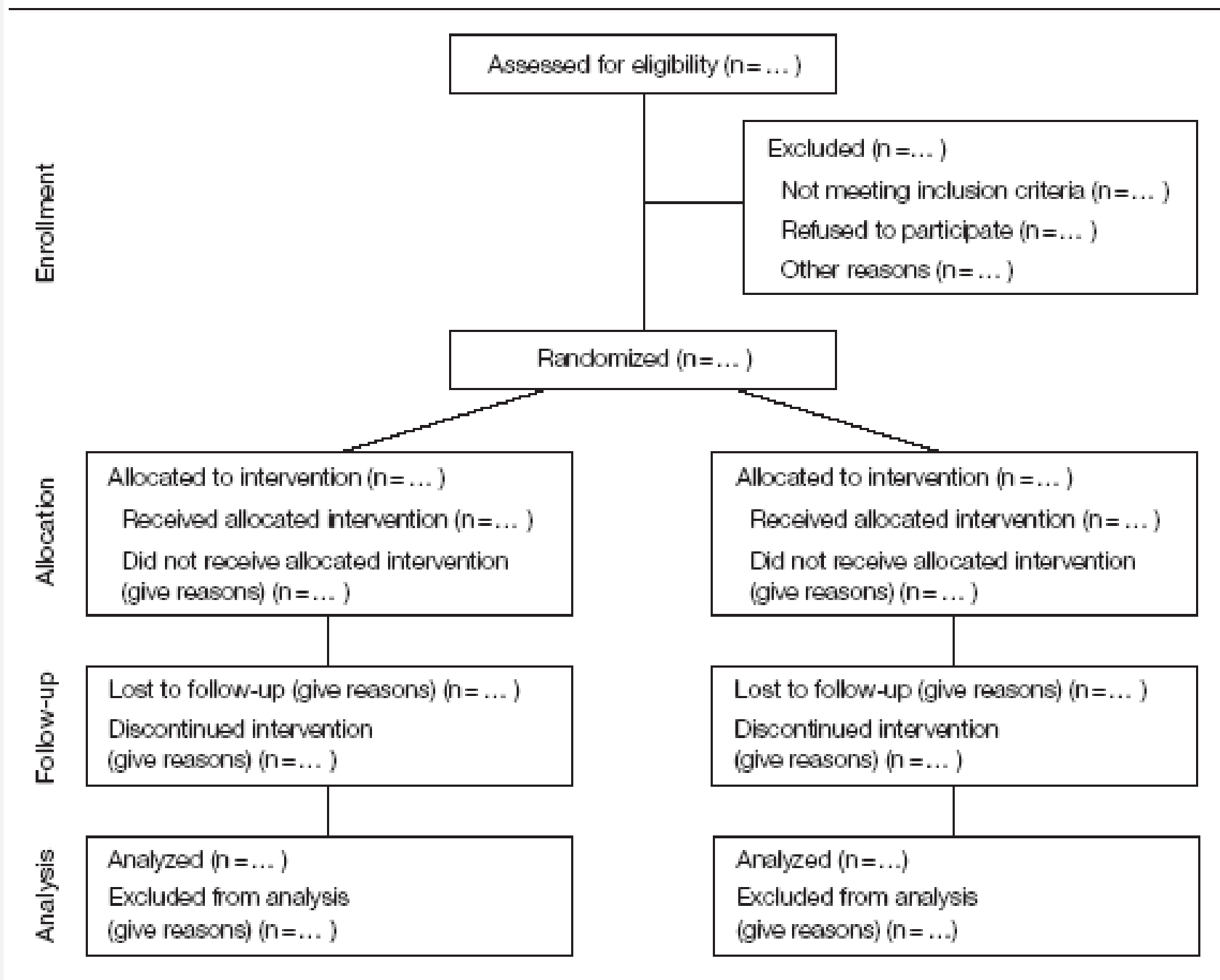
# In Results

- Tell a story
- Use the most logical sequence to present the data (not necessarily the order in which you did the experiments)
- Just report the data - do not include interpretation or comparison to literature
- No duplication of data

# In Clinical Trials: Participant flow

- Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.

**Figure.** Flow Diagram of Subject Progress Through the Phases of a Randomized Trial



# Remember ...

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- All important adverse events or side effects in each intervention group.

# your results, not your tables

- Confusing and disjointed Results sections often arise because the writer does not have a clear idea of the story she/he intends to tell.
- When preparing to write your results, decide on the elements of the story you wish to tell, then choose the subset of text, figures, and tables that most effectively and concisely conveys your message.
- Organize this subset of tables and figures in a logical sequence; then write your story around them.

# Warning signs in result section

- Irrelevant “significant” findings/correlation coefficients
- Baseline differences not discussed
- Normality not evaluated/reported
- Drop-outs and non-responders not mentioned
- Ambiguity on outlier handling
- CI not mentioned
- Unjustified timeframe
- Subgroups without theoretical justification

# Does the y-axis start at zero?

- The y-axis should always begin at **zero**. If this is not so, someone is trying to make you believe that one of the groups has reached the **lowest rate or number possible** when this is not the case.

# Four possible outcomes from any study

1. Difference is clinically important and statistically significant i.e. important and real.
2. Of clinical importance but not statistically significant. sample size too small.
3. Statistically significant but not clinically important i.e. not clinically meaningful.
4. Neither clinically important nor statistically significant.

# Remember...

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- Point estimates should be accompanied by distributions
- Report only what you found; hold all discussion of the significance of the results for the Discussion section.
- Cite tables and figures without describing in detail how the data were manipulated.
  - Explanations of this sort should appear in a legend or caption written on the same page as the figure or table.

# Discussion

# The function of the Discussion is:

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- ❖ To write Briefly & summarize your principal finding
- ❖ Implications of your results for other researchers
- ❖ Interpret findings in light of the literature
- ❖ Reconcile findings with the literature
- ❖ Limitations of your study
- ❖ Conclusions

# Discussion

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- explain what the results mean or why they differ from what other workers have found.
- interpret your results in light of other published results
- Relate your discussion back to the objectives and questions you raised in the Introduction section.
- Make statements that synthesize all the evidence
- Limit your conclusion to those from the present study

# Paragraphs in Discussion

- 1st paragraph
  - ▣ Introduce broad Idea
  - ▣ State major findings
- 2nd paragraph
  - ▣ Explicit rationale
- Last paragraph
  - ▣ Conclusion
  - ▣ Sugestions

# Mechanics of Writing- Discussion

- Construct parallel to results
- Interpretation of data
- Relate your results to the findings of other investigators
- Summary paragraph at end - include significance of results
- Avoid redundancy with results and introduction sections

# Discussion

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- Do your results provide answers to your testable hypotheses?
- If so, how do you interpret your findings?
- Do your findings agree with what others have shown?
- If not, do they suggest an alternative explanation or perhaps a unforeseen design flaw in your experiment (or theirs?)

# Discussion

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- Given your conclusions, what is our new understanding of the problem you investigated and outlined in the Introduction?
- Explain weaknesses, shortcomings. Be fair: this will build trust. Don't over-criticize yourself, don't go to unnecessary details.

# Discussion

- Organize the Discussion to address each of the experiments or studies for which you presented results.
- discuss each in the same sequence as presented in the Results, providing your interpretation of what they mean in the larger context of the problem.
- If warranted, what would be the next step in your study, e.g., what experiments would you do next?
- Reverse of Introduction (pyramid)
- focus on the BIG PICTURE of the study

# Discussion

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Do not waste entire sentences restating your results; if you need to remind the reader of the result to be discussed, use "bridge sentences" that relate the result to the interpretation:

# Good discussions ...

- Address every key finding of the study
- Present the finding in terms of what is known
- State why this study is different
- State why the results concur/ disagree with current knowledge
- Justify differences
- Point out future directions/ continued knowledge gaps

# Style

- Use the *active voice* whenever possible in this section.
- Be *concise* and make your points clearly.
- Use of the *first person* is okay, but too much use of the first person may actually distract the reader from the main points.
- 2-3 paragraphs, <450 words

# Some notes

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- How would you change your experiment to make it better?
- What new questions did this experiment make you think of?
- If you made mistakes in your experimental design, did you discuss them and how to fix it for next time.

# Remember

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- never generalise your results beyond the type of participants
- never draw unjustified conclusions

Title

# Title

- First & most of the times the **only part of an article** that readers and editors **see and read**.
- Key elements that advertises the paper's contents
  - ▣ **Informative** and **Specific**
- Maybe helpful to choose the title **when the paper is complete**

# Title

- ❑ Short and simple
- ❑ Include study design
- ❑ Include time and place if necessary
- ❑ Begin with a keyword
- ❑ Avoid abbreviations
- ❑ Remove empty phrases such as “ A study of...”
- ❑ Use Subtitles (notice number of words) “Exercise and Coronary Heart Disease: Framingham Offspring Study”

# Title can be

- ⑩ **Indicative titles** indicate the subject matter of a paper but give no indication of any results obtained or conclusions drawn e.g. *The effectiveness of bed nets in controlling mosquitoes at different seasons of the year.*
- ⑩ **Informative titles** give an indication of results achieved and conclusions drawn as well as the subject matter of the paper e.g. *Bed nets control mosquitoes most effectively when used in the rainy season.*
- ⑩ **Question-type titles**
  - ⑩ This type of title obviously asks a question. e.g. *When are bed nets most effective when used to control mosquitoes?*
- ⑩ **Main-subtitle (series) type**
  - ⑩ This approach is not liked by editors of scientific journals because if they accept the first paper they will be duty bound to accept sequels. e.g. *The effect of bed nets on mosquitoes: 1.Their effectiveness when used only in the rainy season.*

# General suggestions for titles:

- Concise and precise
- Informative and descriptive
- Not misleading or unrepresentative
- Specific – for example, include type of study and numbers (if large)
- Words appropriate for classification
- Use less hyphens
- More succinct titles have higher citation counts.
- A title must be factually correct
  
- Country name? City name?

# & Finally check:

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- Is it accurate?
- Is it in any way misleading?
- Does it contain essential key words?
- Is it interesting?

# Abstract

# The Abstract

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- an overview of the paper.
- should make sense both when read alone and when read with the paper
- The overview should present the main story and a few essential details of the paper for readers who read only the abstract and
- It is usually written after the manuscript is written.

# Abstract

- Summarizes the **major findings** in the broad context of the work
- Consists of **two or three sentences** of topic introduction
- Selected results (not all but **the most important**)
- Concludes with implications of work

# The abstract of a paper should state concisely:

- the **question** that was asked,
- what was done **to answer** the question,
- what was **found** that answers the question, and
- the **answer** to the question.

# Abstracts

- Most journals limit the length of the abstract (**usually to 250 words or less**) “Uniform Requirements for Manuscripts Submitted to Biomedical Journals”
- For **un-structured abstracts**, limit the abstract to **150 words or less**.
- If no limit is stated, make your abstract **no longer than the abstracts in recent issues** of the journal.

# In unstructured method

- Write the abstract as one paragraph.
- Use the techniques of continuity to make the paragraph flow. Use signals to indicate the parts of the abstract:
- Signal what you found by "We found that" or something similar.

# In unstructured method

- Signal the answer by "We conclude that" or "Thus" or something similar. Signal implications by "We suggest that" or something similar.
- The question and what was done can usually be written in one sentence in "the form "To determine X, we. ...". If the question and what was done are in separate sentences, use signals such as "We asked whether. .." (question) and "To answer this question, we. .." (what was done).

# In summary:

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- The abstract should provide an **overview of the main story** and a **few essential -details**.
- The abstract should be **clear** both to
  - readers who read the paper
  - readers who do not read the paper.

# Abstract Writing

- Use **present tense** verbs for the **question and the answer**.
- Use **past tense** verbs to state **what was done and what was found**.
- Be careful **not to omit the question**, not to state the question vaguely, and not to state an implication instead of the answer .

# Abstract Writing

- To ensure that the question is specific rather than vague, check the question against the answer: use the same key terms for the independent and dependent variables; keep the same point of view; and, to anticipate the answer, use the same verb in the question as in the answer.
- If you give a  $p$  value, also give data (for example, mean(SD) and the sample size ( $n$ )).

# Abstract Writing

- Omit details [unnecessary details of methods, exact data (give percent change),  $p$  values, "significantly"].
- Avoid repetition (use a category term in what was done and name the variables in what was found; state "mean  $\pm$  SD" only once).
- Use **active voice** instead of **passive voice**.

# Keywords

- Select terms that you would look up to find your own paper and that would attract the readers you hope to reach.
- Select current, specific terms, preferably medical subject headings (MeSH), that name important topics in your paper .
- Use phrases as well as single words.
- If the journal asks you to supply only terms that are not in the title of the paper, do so
- If necessary, include a term as an indexing term even if the term does not appear in your paper .

# Check list for Abstract

- Background, methods, results, discussion?
- Key features mentioned?
- Anything that does not appear in full text?
- Results in words?
- Conclusion: justified? objective?
- Meaningful interpretation
- Follows the guidelines

# References

# References

- Use recent review papers where appropriate to decrease the number
- Get a hard copy of every reference in the manuscript and make sure the referenced paper says what you say it does! Don't use abstracts!
- Proof-read the reference list especially carefully as one of your reviewers may be cited!
- Use EndNote or other bibliographic software
- Use the Internet

# References

- Appropriate format
- Only 1 or 2 references per point
- Don't over self-cite
- Avoid textbooks & conference abstracts.
- Avoid referencing to thesis & dissertations
- Avoid using the references list of your reference
- Select carefully, balance authors used

# Main Important Referencing Styles

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1. **Author-Date Style**  
(Harvard Style)
2. **Numeric Style**  
(Vancouver Style)

# Author-Date Style system

- In-Text citations:
  - ▣ Cite your sources within your text by giving the **author's surname(s), year of publication**, and (when appropriate) page numbers
  
- Reference List Bibliography
  - ▣ All references are listed in author/date alphabetical order:

# Numeric system

- In-Text Citations:
  - ▣ Each citation in the text is given a number in brackets:
  
- Reference List Bibliography
  - ▣ References are listed in number order in the bibliography, & cited by that number each time they are referred to in the text.

# References

- Check specific referencing style of journal
- Should reference:
  - ▣ Peer-reviewed journal articles, abstracts, books
- Should not reference:
  - ▣ Non-peer-reviewed works, textbooks, personal communications

# Reference management software

- ⑩ Reference management software, citation management software or personal bibliographic management software is software for authors to use for recording and utilizing bibliographic citations (references).
- ⑩ Once a citation has been recorded, it can be used time and again in generating bibliographies, such as lists of references in articles.
- ⑩ These software packages normally consist of a database in which full bibliographic references can be entered, plus a system for generating selective lists or articles in the different formats required by publishers and learned journals.
- ⑩ Modern reference management packages can usually be integrated with word processors so that a reference list in the appropriate format is produced automatically as an article is written, reducing the risk that a cited source is not included in the reference list.

# General considerations

# How to report numbers

Numbers less than 10 are words.

Numbers 10 or more are numbers.

Words not numbers begin a sentence.

Be consistent in lists of numbers.

Numbers less than 1 begin with a zero.

Do not use a space between a number and its per cent sign.

Use one space between a number and its unit.

Report percentages to only one decimal place if the sample size is larger than 100.

In the study group, eight participants underwent the intervention.

There were 120 participants in the study.

Twenty per cent of participants had diabetes.

In the sample, 15 boys and 4 girls had diabetes.

The *P* value was 0.013.

In total, 35% of participants had diabetes.

The mean height of the group was 170 cm.

In our sample of 212 children, 10.4% had diabetes.

# How to report numbers

Do not use decimal places if the sample size is less than 100.

Do not use percentages if the sample size is less than 20.

Do not imply greater precision than your measurement instrument.

For ranges use “to” or a comma but not “-” to avoid confusion with a minus sign and use the same number of decimal places as the summary statistic.

Rules for data numbers do not apply to citations to the literature.

In our sample of 44 children, 10% had diabetes.

In our sample of 18 children, two had diabetes.

Only use one decimal place more than the basic unit of measurement when reporting statistics (means, medians, standard deviations, 95% confidence interval, interquartile ranges, etc.)

The mean height was 162 cm (95% CI 156 to 168).

The mean height was 162 cm (95% CI 156, 168).

The median value was 0.5 mm (interquartile range -0.08 to 0.7).

The range of heights was 145 to 170 cm.

The page range was 145-70.

# Orwell's Six Rules for Writing

- ❑ *Never use a metaphor, simile, or other figure of speech which you are used to seeing in print.*
- ❑ *Never use a long word where a short one will do.*
- ❑ *If it is possible to cut a word out, always cut it out.*
- ❑ *Never use the passive where you can use the active.*
- ❑ *Never use a foreign phrase, a scientific word, or a jargon word if you can think of an everyday English equivalent.*
- ❑ *Break any of these rules sooner than say anything outright barbarous.*

# Your message

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- You have no clear message? Perhaps not ready for writing a paper
- You have more than one message? Which one is the most important one? Do you need more than one paper?

# Remember

---

- ❑ Basic grammar and spelling is essential
- ❑ You are responsible for submitting high quality manuscripts.
- ❑ Do not turn in a first draft to any one.
- ❑ Some times you need to put a piece of writing away for a few days before you can approach it dispassionately enough to rework it.
- ❑ Think about the structure of manuscript and paragraphs.

# Paragraph

---

- A paragraph should begin with a topic sentence that sets the stage clearly for what will follow.
- Make topic sentences short and direct. Build the paragraph from the ideas introduced in your topic sentence and make the flow of individual sentences follow a logical sequence.

# Tenses

- Problems of inappropriate or inconsistent tenses are common in writing.
  - ▣ **What you, or others, did in the past should be stated in the past tense** (e.g. data were collected)
  - ▣ Events or **objects that continue to happen or exist can be described in the present tense** (e.g., "in this paper, I examine..... The data reject the hypothesis that....."). Whatever tense you choose, be consistent.
- **When describing methods and results, you should use the past tense.** The present tense is appropriate for accepted facts, such as the background information presented in the Introduction. In addition, you may use the **present tense when you discuss your results and conclusions.** Looking over other scientific papers may help you answer questions you might have on this topic.

# Practical tips

- You should **avoid abbreviations** by writing out the full word (minimum, October, first, temperature, ...). Exceptions include common terms like ATP and DNA, units of measure (m, g, cm, °C), and mathematical or chemical formulas.
- Sentences should never begin with an abbreviation or an acronym.
- You may wish to **introduce an acronym** for a term that is repeated often: if your paper deals with soybeans, *Glycine max*, you may use the full scientific name once and substitute *G. max* thereafter.
- **Chemical elements are not proper nouns**, so do not capitalize them. Only the first letter of the symbol is a capital letter: nitrogen (N), carbon (C), calcium (Ca).

# Practical tips

- In formal writing, you should **never use contractions** (didn't, can't, haven't...).
- The word **"data"** is plural, as in "the data were collected on January 21, 2001."
- **Direct quotes should be avoided**, unless you are presenting another author's specific definition or original label.
- You should **review your writing** to make sure that each sentence presents one or two clear ideas. This will also help you organize sentences within paragraphs in a logical order.

# Practical tips

- In science, the word "**significant**" implies the result of a statistical test. You should **analyze your results to determine whether they are statistically significant** and report the test you used.
- **Do not use slang**. Try to use precise, scientific terms where possible (without unnecessary jargon) and avoid colloquialisms and figures of speech: "somewhat" rather than "sort of," "many" or "a great deal" instead of "a lot."
- Your **word processor's spell-check and/or grammar-check function is not error-free**.
- All **units of measure must be metric or SI** (international System).

# Punctuation

- **Colon (:) and semi colon (;)**

- A colon is used when a list or explanation follows, a semi colon is used to separate two or more related clauses provided each clause forms a full sentence.

- **Commas**

- A comma is put in a sentence to denote a brief pause between groups of words, or to separate subclauses or to separate all items in a list except for the last two;

# A Few Rules

- The first time you use an abbreviation, define it
- When you give the commercial source for a reagent, the first time you cite the source include the location of the company (city and state)
- Make sure the subject and verb agree in every sentence
- No exclamation points!



# PUBLISH

Dr L. Ghalichi  
Epidemiologist  
Iran University of Medical Sciences

# Where to Publish?

# Publish

---

How many journal?

How many annual articles?

# Databases

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- General Databases  
(Comprehensive OR Core Databases)
  
- Specialized Databases  
(Subjects Specified Databases)

# General Databases (Comprehensive OR Core Databases)

- Medical Sciences
  - ▣ Medline
  - ▣ Embase
  - ▣ Scopus
  
- All Sciences
  - ▣ Web of Sciences

# Specialized Databases (Subjects Specified Databases)

- Biological Abstracts
- International Pharmaceutical Abstract
- PsychInfo
- CINAHL
- Chemical Abstracts
- Agricola
- Econlite
- AIDSline

# Web of Science

- “Web of Science” is the database name provided by “Institute of Scientific Information” famous in our country as “ISI”.
- The complete company name is Thomson Reuters ISI.
- The Web of Sciences is the same database that we calculate the Journals Impact Factor from its data.

# Web of Science

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- If a journal is in Web of Science, it means it should have Impact Factor & vice versa.
- Don't confuse Web of Sciences Journals with ISI Master list Journals !

# The Journal Impact Factor

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- The Journal Impact Factor is calculated for those journals only which are indexed & included in Web of Sciences Databases, NOT more !
- The database which contain the Journal Impact Factors is Journal Citation Report abbreviated JCR.

# What is Journal Impact Factor?

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The average citation frequency for articles published in a journal, or how many times, on average, during the study year the articles that appeared in the 2 preceding years of that journal received citations in other (ISI) indexed journals only.

# Impact Factor Calculation

Citations in the current JCR year to articles published in the previous two years divided by the number of articles published in the previous two years.

$$\text{IF}(2014) = \frac{\text{Citations in 2014 to articles published in 2013 + 2012}}{\text{Total 2013 + 2012 Papers}}$$

# How to Find Impact Factors?

- Directly from Journal Citation Report Database through ISI.
- Using the Excel Datasheets, prepared especially for this matter.

# English or Another Language?

- Impact factor bias toward English journals
- Need an English speaking colleague, not a translator
- Size of audience
- Most journals will help with copyediting but reviewers need readable English
- Option: Publish in several languages (with editors' permission)

# Consider, but do not be fooled by, the Journal Impact Factor (JIF)

- JIF is determined by the frequency at which articles in that journal were cited
- high impact journals have more prestige, but JIF depends on other things, like number of co-authors and indexing
- non-English journals are at a disadvantage
- number of databases indexing the journal will determine who sees abstract of article

# Consider these practical aspects:

---

- How long to get the article peer reviewed?
- How long between acceptance and publication?
- Special audiences
- How much editorial support does it give?

# Finding and choosing an appropriate journal to Submit

- Where to look for the journal:
  - ▣ Personal experience
  - ▣ Colleagues' experience
  - ▣ Library
  - ▣ Citations in Databases
  - ▣ Online Resources

# Prepare for Submit

# Title Page

---

Based on “Instruction to Authors”

- Title
- Running Title
- Authors
- Affiliation
- Organization
- Correspondence

# Title & Running title

- On the title page, the main title is typed in uppercase and lowercase letters.
- If the main title is more than one line, use a double space between the lines.
- An abbreviated version of the title is called a running title, which may be used for identification of the report on subsequent pages.
- Usually 30-40 including white spaces

# Authors

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- Full name, highest academic degree, title/s, position and address
- Some journals limit number of authors to 12
- Write The name of authors in separate lines

# Corresponding Author

---

- Name
- Affiliation
- Organization/Department
- Postal Address
- Phone                      Fax
- E-mail
- Date on which the paper was submitted

# Review

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- Both in terms of science and the presentation
- Coauthors or coworkers
- When papers are badly constructed, reviewers tend to fix the immediate problems without focus on content
- Drafts must be at highest standard that you can
- Serial or parallel circulation
- First author must decide to accept or reject the suggestions

# Critical Appraisal Tools

---

- Why do we need them?
- Where we can find them?

# Instruction to authors and checklists

- Its better to read “Instruction to authors” of your selected journal before writing the paper
- Commonly used checklists:
  - ▣ Randomized controlled trials
  - ▣ Qualitative studies
  - ▣ Statistical reviews
  - ▣ Economic evaluation
  - ▣ Systematic review

# Creating a good impression

---

## Visual topic changes

- Use subheadings to divide sections
- Use new paragraphs for new topics

# Before submit

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- One last proofread
- One last spell check
- One last walk through the checklists
- Instruction to Authors

# Covering letter

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- Write a cover letter, short and direct, addressed to the editor
- Polite
- Why Journal chosen
- Importance of paper
- Brief

# Covering letter

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- Describe the paper
- Repetitive publication and duplicate submission
- Conflict of interest
- Corresponding author
- Suggest reviewers

# Covering letter

## Example of a letter to the editor

Dear Editor

Please find enclosed a paper entitled 'Exact statistical methods for presenting data of rare diseases' for consideration for publication in your journal.

The data included in this manuscript **have not been published** previously and **are not under consideration** by any other journal. A form with consent to publication **signed by the authors** is enclosed. All authors have read this final manuscript and have given their approval for the manuscript to be submitted in its present form.

(continued)

# List of Potential Reviewers

1) Dr. Joe Smith  
Duke University Medical Center  
Cell Biology  
438 Nanaline Duke/Box 3709  
Durham, NC 27710  
Phone: 919-684-8040  
Fax: 919-684-8106  
e-mail: [j.smitht@cellbio.duke.edu](mailto:j.smitht@cellbio.duke.edu)

2) Dr. Virginia Jones  
Vanderbilt University  
Pathology  
1310 24<sup>th</sup> Ave S.  
Nashville, TN 37212-2637  
Phone: 615-327-4751 X 5499  
Fax: 615-321-6305  
e-mail: [jonesv@aol.com](mailto:jonesv@aol.com)

3) Dr. Tony D. Soprano  
Southampton General Hospital  
Child Health  
Level G (803) Center Block  
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Southampton, SO16 6YD United  
Kingdom  
Phone: 44-23 8079 6161  
Fax: 44-23 8079 6378  
e-mail: [adp@soton.ac.uk](mailto:adp@soton.ac.uk)

4) Dr. David Mitchell  
Department of Pediatrics  
Milton S. Hershey Medical Center  
H085 Hospital  
Hershey, PA 17033  
Phone: 717-531-5925  
Fax: 717-531-8985  
e-mail: [dsp4@psu.edu](mailto:dsp4@psu.edu)

5) Dr. Arnold Smith  
University of Missouri-Columbia  
Department of Molecular Microbiology and  
Immunology  
M616 Medical Sciences Building DC 04400  
Columbia, MO 65212  
Phone: 573-882-8989  
Fax: 573-882-4287  
e-mail: [SmithAL@missouri.edu](mailto:SmithAL@missouri.edu)

# Authorship & Publication Ethics

# Authorship

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- Authors are listed to provide a public record of responsibility and credit for the work
- Only those who can take both **responsibility** and **credit** for a work should be authors

# Authorship Policies Try to

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- **Ensure** that **all** those who deserve authorship are listed as authors
  
- Ensure that those who do **not** deserve authorship are **not** listed as authors

# Authorship

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data **AND**
2. Drafting the article or revising it critically for important intellectual content **AND**
3. Final approval of the version to be published

**All 3 conditions should be met for assigning authorship**

(Consensus Statement, International Council of Medical Journal Editors)

# Acknowledgments

- All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section
  - who provided purely technical help
  - writing assistance
  - department chair who provided only general support
  - Financial and material support

# How to avoid problems with authorship?

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1. Follow the international guidelines.
2. Agree before starting
3. Don't add a senior author to improve the chances of publication
4. Agree on who will be corresponding author.

# Types of Authorship

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- Gift Authorship
- Ghost Authorship

# Order of authors

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- Alphabetic
- Based on participation

# What is Plagiarism?

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According to Webster's New World Dictionary, to plagiarize is to "take the ideas, writings, etc. from another and pass them off as one's own"

Plagiarism is the act of presenting the words, ideas, images, sounds, or the creative expression of others as your own.

# How to avoid Plagiarism?

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1. Quoting
2. Re-wording or Re-phrasing

# Direct Quotes

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- If you use someone else's writing without putting it in quotes, you have blatantly plagiarized.
- Even if you add the source in your bibliography, it is still plagiarism !

# Paraphrasing

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- Be careful about rewriting someone else's words. If your sentences use many of the same words and grammatical structure as the original source, it could be construed as plagiarism. Just put the text in your own words.

# When rewording...

- Be sure you are not just rearranging or replacing words.
- Rewrite the phrase in your own words and credit the original source.
- Double check what you have wrote by comparing it with the original writing.

# Plagiarism Detection

- Software or websites
- Free or not

# Fraud

---

- Falsification of Data
- manipulate the experiments or the data

# Guidelines for Publication

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- Widely cited guidelines for publication written by the International Committee of Medical Journal Editors. Guidelines can be found at
  - [www.icmje.org](http://www.icmje.org)

# Guidelines for Publication

- Avoid misrepresentation in publications
  - Authors responsible to publish accurate, complete, clear, and unbiased work
- Publish manuscripts that represent new and substantial findings
  - Avoid fragmentary publication – dividing research findings into the smallest publishable units

# Guidelines for Publication

- Avoid redundant manuscript submission & publication
  - ▣ Submission of a paper provisionally gives the journal copyright of the work
  - ▣ Readers may be misled into thinking the research represents two separate data sets
  - ▣ Readers may be led to think that a study has been successfully repeated

# Guidelines for Publication

- Do not plagiarize!
  - Always credit the work of others
  - Be sure to cite sources
  - Include all cited sources in the reference list and vice versa
  - Obtain permission to include figures, models, graphs, etc.

# Guidelines for Publication

---

- Acknowledge those who contribute to the research but do not qualify for authorship
  - ▣ May provide space, financial support, materials, etc.
  - ▣ Be sure permission to be acknowledged is granted

# Guidelines for Publication

---

- State in the manuscript when research has been approved by institutional review committees
- Acknowledge/disclose in the manuscript any real or perceived conflicts of interest to avoid the appearance of any bias

# Guidelines for Publications

- Admission of error is generally perceived as a sign of integrity and concern for high standards; thus:
  - ▣ Submit letter of erratum to the journal when minor errors are discovered in a manuscript
  - ▣ Submit a letter of correction to the journal if unintentional errors are found that undermine part of the manuscript
  - ▣ Submit a letter of retraction to the journal when unintentional errors or errors of misconduct are great enough to invalidate the entire manuscript

# Publication Ethics

- Redundant Publication
- Duplicate Submission
  
- It is acceptable to publish Full text of an already presented abstract
- Publication in multiple languages is possible if both editors are informed and permit.
- If you have not received any answer from a journal, always retract the manuscript before sending it to another journal

# Remember

- Authors must disclose all sources of funding for their research and its publication.
- Authors must disclose relevant competing interests (both financial and personal)
- Credit for authorship should be based on:
  - substantial contributions to research design, or the acquisition, analysis or interpretation of the data
  - drafting the paper or revising it critically
  - approval of the submitted and final version
- Authors should meet all three criteria.
- Authors must acknowledge individuals who do not qualify as authors but who contributed to the research

# Remember

- Authors must acknowledge any assistance they have received (e.g. provision of writing assistance, literature searching, data analysis, administrative support, supply of materials). If/how this assistance was funded should be described and included with other funding information.
- Authors must declare that the submitted work is their own and that copyright has not been breached in seeking its publication.
- Authors should declare that the submitted work has not previously been published in full, and is not being considered for publication elsewhere.
- The copyright form (see journals webpages)

# Publication Ethics Codes & Protocols

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- You can find more guidelines & protocols of publication ethics in COPE (Committee of Publication Ethics) Website.
- <http://www.publicationethics.org>

# Peer review

# Peer review

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- Manuscripts submitted to peer-reviewed journals are reviewed by experts of the same level.
- Reviewers advise the editor on whether they should be published and what changes are necessary.
- The final decision is made by the editor.
- All correspondences from reviewers or authors will be addressed to the editor.

# Final decision

- Is acceptable for publication
- Is acceptable for publication following minor revisions
- Is acceptable for publication following major revision
- May be reconsidered for publication following major revisions
- May be considered for publication as a letter or a short report
- Is unacceptable for publication

# Editorial decision

- Rejection rate:
  - 15% (pay journals) to 60% (specialist journals) to 90% (NEJM, The Lancet)
- How long does it take? (Choice of journal)
  - BMJ: 70 days
  - JAMA: 117 days
  - Iranian journals?

# Questions journals ask

---

- Is the research question important?
- Is it interesting to our readers?
- Is it valid? A scientifically sound study.

# What editors look for

- Short, clear, precise title
  - Good abstract
  - Good design and methods
  - Clear conclusions
  - Brevity
  - Following the instructions
- 
- They look for articles that may attract attention!

# Dealing with the Journal's Response

# Responding to the editor:

## ⑩ Acceptance without revision

- ⑩ You need **take no further action until the proofs** reach you, except perhaps write a note thanking the editor.

## ⑩ Minor revisions requested (“accepted”)

- ⑩ **Consider the suggestions carefully, and if you agree that they will improve the paper, modify or rewrite sentences or sections as necessary.** Retype any heavily corrected pages before you return the paper to the editor, but enclose the original corrected paper as well as the retyped copies. In your covering letter sent with the revised version, **thank the editor and referees for their help and enclose a list of the substantial changes made in response to their suggestions;** if you have rejected one or more of the recommendations, explain why.

# Responding to the editor:

- ⑩ **Major revisions requested (“further consideration”)**
- ⑩ You will have to **think hard if the effort is worth while**. You may eventually decide that the paper is better as it is, and proceed to try another editor (another journal) in the hope that he will agree with you.
- ⑩ **Rejection**
- ⑩ If the editor says the article is too specialized or outside the scope of the journal, your best course is to **send it to another journal**, first modifying the style to comply with the instructions of that journal.
- ⑩ If the article is rejected because it is said to be too long and in need of changes, consider shortening and modifying it according to the criticism – and then submit it to a different journal (if the editor had wanted to see a shorter version he would have offered to reconsider it after revision!).

# Responding to the editor:

## ⑩ Rejection (continued)

- ⑩ If the editor thinks the findings reported are unsound or that the evidence is incomplete, put the paper aside until you have obtained more and better information, unless you are sure that the editor and his advisers are wrong.
- ⑩ Consider contesting the decision only if you honestly think, after considerable reflection and at least one night's sleep, that the editor and referees have made a superficial or wrong judgement. In this case write a polite letter explaining as briefly as possible why you think the editor should reconsider his decision.

# Dealing with the Journal's Response

## □ **Absolute Rejection**

- Don't take it personal. the manuscript is rejected, not you!
- Contacting the editor is not a recommendation,
- Editorial rejection (fast reject):
  - Sign of a bad journal choice. send it to another journal
- Reviewers comments:
  - Fix the easy and fixable ones.
  - Send it out as soon as possible!

# Dealing with the Journal's Response

- **Conditional acceptance (rejection)**
  - It is yours to lose
  - Within 1-2 weeks decide on if you are going to change the manuscript and how much!
  - Make real changes, say you have done great changes (describe, highlight, etc)
  - Avoid arguments. But you can mention your rationals and references.
  - Thank sincerely, but avoid being obsequious

# Responding to reviews

- Swallow your pride!
- You don't have to accept all, but don't over-reject
- Ask editor about conflicting comments
- However unreasonable the reviewers may seem: be polite!
- Distinguish conditional acceptance from offer to reconsider (and from rejection of course!)
- Use a table to list each of comments, your response and the amended text

# Conflict of Interest

# Potential Conflict of Interest

Possibility from the perspective of an *independent* observer that an individual's private financial interest or family's interests may influence professional actions, decisions, or judgment

- ▣ Not possible or desirable to eliminate
- ▣ Need to manage

# What is conflict of interest?

- Conflict of interest is a set of conditions in which professional judgement concerning a primary interest (such as patients' welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).
- Thompson DF. Understanding financial conflicts of interest. *N Engl J Med* 1993; 329: 573-576

# What is conflict of interest?

- Conflict of interest is a **condition** not a **behaviour**.
- Having a conflict of interest is not, in and of itself, evidence of wrongdoing
- For many professionals, it is virtually impossible to avoid conflicts of interest from time to time
- you might want to disclose another sort of competing interest that would embarrass you if it became generally known after publication

# Four Categories of Conflicts

193

- **Investigator Financial Conflict of Interest**
  - Financial interests of investigator may suggest a presumption of bias in carrying out research; will the personal financial interests of the researcher have a potential effect on the quality, outcome and/or dissemination of the research undertaken?
- **Investigator Conflict of Commitment**
  - Established by organization's policy on duty owed institution as primary employer
- **Senior Officer/Supervisory Conflict of Interest**
  - Influence of senior officers representing their self interest or interest on behalf of the institution may favor one research program over another, one sponsor over another; sr. officers may try and influence licensing negotiations; may cause confusion for students
- **Institutional Conflict of Interest**
  - Conflict between institutional mission of education, dissemination of knowledge etc and interest as an investor, equity holder in institutional start-up companies, venture funds etc.

# Do you have a conflict of interest?

- ❑ Reimbursement for attending a symposium
- ❑ A fee for speaking
- ❑ A fee for organising education
- ❑ Funds for research
- ❑ Funds for a member of staff
- ❑ Fees for consulting
- ❑ Employment
- ❑ Holding stocks
- ❑ close relationship or strong antipathy
- ❑ academic link or rivalry
- ❑ Membership of a political party or special interest group

# Competing interest statement

- Competing interests:
  - ▣ RS has been reimbursed by \*\*\*\* company, the manufacturer of \*\*\*, for attending several conferences
  - ▣ TD has been paid by \*\*\*\* company for running educational programmes and has her research registrar paid for by the company;
  - ▣ JS has shares in the \*\*\*\* company.

# Why don't authors declare it?

- Some journals don't require disclosure
- The culture is one of not disclosing
- Authors think that it's somehow "naughty"
- **Authors are confident that they are not affected by conflicts of interest**

# Does conflict of interest matter?

- ❑ Financial benefit makes doctors more likely to refer patients for tests, operations, or hospital admission, or to ask that drugs be stocked by a hospital pharmacy.
- ❑ Original papers published in journal supplements sponsored by pharmaceutical companies are inferior to those published in the parent journal.
- ❑ Reviews that acknowledge sponsorship by the pharmaceutical or tobacco industry are more likely to draw conclusions that are favourable to the industry.

# How to respond to conflict of interest?

- “If in doubt, disclose.”
- Sometimes the conflict will be so strong that it will forbid participation
- The danger of trying to eradicate conflict of interest is that it may encourage deception

# Conclusions

- ❑ Concern about conflict of interest is not just political correctness
- ❑ Conflict of interest has an important impact on the information reaching health professionals and the public and on patient care
- ❑ Conflict of interest is very common in medicine
- ❑ Most conflicts of interest in medicine are not disclosed
- ❑ Yet disclosure should be the main response to conflict of interest
- ❑ We in health care need to do a better job of managing conflict of interest



# **PEER REVIEW & CRITICAL APPRAISAL**

**L. Ghalichi, MD, PhD**

# Peer review

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- Manuscripts submitted to peer-reviewed journals are reviewed by experts who advise the editor on whether they should be published and what changes are necessary.

# Peer Review - Functions

---

- To Protect
  - i) The author from publishing &
  - ii) The subscriber from reading

Material of insufficient quality

# Editorial decision

An editorial committee may decide that a paper:

- Is acceptable for publication
- Is acceptable for publication following minor revisions
- Is acceptable for publication following major revision
- May be reconsidered for publication following major revisions
- May be considered for publication as a letter or a short report
- Is unacceptable for publication

# Editorial decision

- Rejection rate: 15% (pay journals) to 60% (specialist journals) to 90% (NEJM, The Lancet)
- How long does it take? (Choice of journal)
  - BMJ: 70 days
  - JAMA: 117 days
  - Iranian journals?

# Questions journals ask

---

- Is the research question important?
- Is it interesting to our readers?
- Is it valid? A scientifically sound study.

# What editors look for

---

- Short, clear, precise title
- Good abstract
- Good design and methods
- Clear conclusions
- Brevity
- Follow instructions

# What reviewers look for

---

- Good design and methods
- Simple tables and figures
- Logical organisation
- Brevity
- Balance
- Appropriate statistics
- Their papers

# Problems with peer review

---

- Slow
- Expensive
- A lottery
- Ineffective
- Biased
- Easily abused
- Can't detect fraud

# Evaluating a manuscript

# Title

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- Read the title and check that you understand its meaning. Sometimes titles are inaccurate and do not reflect the content of the paper which follows.
- Watch for cryptic titles. Sometimes a useful paper may be hidden behind an indifferent title.
- Never rely on the title alone to accept or reject a paper for more detailed reading.

# Authors

- Range of expertise: professional backgrounds with address
- Research center?
- Principle researcher
- Number of authors
- Have any of the authors obvious connections with the drug industry?

# abstract

- This is a synopsis of the paper, which should give the **objective** of the study, the **methods** used, the **results** obtained and the **conclusions** reached.

Beware of the following warning signs:

- Confusion and possible contradictory statements
- Profusion of statistical terms
- Disparity between the number of subjects mentioned in the summary and the number in the paper

# Introduction

---

- Check that a brief review of available background literature is provided and that the question being asked in the study follows logically from the available evidence.

# Introduction

- General, concise description of problem
  - ▣ background to the work
  - ▣ previous research
- Where that work is deficient
  - ▣ how your research will be better
- State the hypothesis
- About 3 to 4 paragraphs

# Methods

---

- Study design
- Participants
- Ethical approval
- Sample size
- Questionnaires
- Interventions
- Clinical assessments
- Statistical methods

# Six essential questions in methodology

---

- 1. Was the study original?**
- 2. Who is it about?**
- 3. Was the design of the study sensible?**
- 4. Was bias avoided?**
- 5. Was assessment "blind"?**
- 6. Were preliminary statistical questions dealt with?**

# 1. Was the study original?

- Is this study bigger, continued for longer, or otherwise more substantial than the previous one(s)?
- Is the methodology of this study any more rigorous ?
- Will the numerical results of this study add significantly to a meta-analysis of previous studies?
- Is the population that was studied different in any way?
- Is the clinical issue addressed of sufficient importance, and is there sufficient doubt in the minds of the public or key decision makers?

## 2. Who is it about?

- How recruited?
  - ▣ *Recruitment bias*
- Who included?
- Who excluded?
- Studied in “real life circumstances” or not?
- Generalizable?

### 3. Was the design of the study sensible?

- What is the design?
- Is it appropriate?
- Is it performed correctly?

## 4. Was bias avoided?

- was bias adequately accounted?

RCT – method of randomisation, assessment ? truly blind.

Cohorts – population differences

Case control – true diagnosis, recall (and influences)

## 5. Was assessment "blind"?

- Blindness
- Concealment

## 6. Were preliminary statistical questions dealt with?

- **Statistical tests**
- **The size of the study**
  - “power”
- **The duration of follow-up**
  
- **The completeness of follow-up**
  - “drop-outs”

# Results

## What was found?

- Should be logical
  - ▣ Simple to complex
  - ▣ Positive to negative

# Cheat on statistical tests

- ❑ Subgroups are not rational
- ❑ baseline differences not accounted for
- ❑ Normality not evaluated
- ❑ withdrawals and non-responders not considered
- ❑ Correlations not rational
- ❑ Outliers maltreated
- ❑ Confidence intervals not mentioned
- ❑ Duration not rational

# Graphs

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- The  $y$ -axis should always begin at **zero**. If this is not so, someone is trying to make you believe that one of the groups has reached the **lowest rate or number possible** when this is not the case.

# Discussion

- Check that the progress in argument to the conclusion is logical and also that any doubts or inconsistencies which have been raised in your mind by earlier parts of the paper, are dealt with.
- Are limitations mentioned?
- Authors' **speculations** should be clearly distinguished from results, and should be seen as **opinion not fact**.

# Bibliography

- If you find statements in the paper which you consider to be important check that a **reference** is provided.
- Be suspicious if no reference is given, or if the references which are provided are dated, or predominantly in obscure journals.

# Acknowledgment

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- Who? (and what)?
- Source of funding? (conflict of interest)

# Critical Appraisal tools

# What is critical appraisal?

- Critical appraisal is the **assessment** of evidence by **systematically** reviewing its **relevance**, **validity** and **results** to specific situations.

Chambers, R. (1998).

Critical appraisal is <u>not</u> :	Critical appraisal is:
× Negative dismissal of any piece of research	✓ Balanced assessment of benefits and strengths of research against its flaws and weaknesses
× Assessment of results alone	✓ Assessment of research process and results
× Based entirely on detailed statistical analysis	✓ Consideration of quantitative and qualitative aspects of research
× To be undertaken by expert researchers/statisticians only	✓ To be undertaken by all health professionals as part of their work

# Critical appraisal helps the

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- Decide how trustworthy a piece of research is (*validity*)
- Determine what it is telling us (*results*)
- Weigh up how useful the research will be (*relevance*)

# Three preliminary questions

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- **Why** was the study done and what hypothesis was being tested?
- **What** type of study was done?
- **Was** the study **design appropriate**?

# Why was the study done?

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- **research question**
- **hypotheses**

# Was the study design appropriate?

- Broad fields of research
  - *Therapy*: testing the efficacy of drug treatments, surgical procedures, alternative methods of service delivery, or other interventions. Preferred study design is **randomized controlled trial**
  - *Diagnosis*: demonstrating whether a new diagnostic test is valid (can we trust it?) and reliable (would we get the same results every time?). Preferred study design is **cross sectional survey** in which both the new test and the gold standard are performed

# Was the study design appropriate?-2

- ▣ *Screening*: demonstrating the value of tests which can be applied to large populations and which pick up disease at a presymptomatic stage. Preferred study design is **cross sectional survey**
- ▣ *Prognosis*: determining what is likely to happen to someone whose disease is picked up at an early stage. Preferred study design is longitudinal **cohort study**
- ▣ *Causation*: determining whether a putative harmful agent, such as environmental pollution, is related to the development of illness. Preferred study design is **cohort or case-control study**, depending on how rare the disease is, but **case reports** may also provide crucial information

# Three questions

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## Valid?

Is the methodology appropriate to answer the question.

Is it carried out in a sound way, eliminating bias and confounding?

## Reliable?

Are the results real or because of chance?

## Applicable?

Will the results help locally?

# STROBE Statement

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- **ST**rengthening the **R**eporting of **OB**servational studies in **E**pidemiology
- [www.strobe-statement.org](http://www.strobe-statement.org)

# Observational studies

# STROBE Statement

- Strengthening the Reporting of OBservational studies in Epidemiology
- Many journals refer to the STROBE Statement in their Instructions for Authors.
- Provides recommendation for each section (22 items)

# Available STROBE check-lists

- STROBE checklist for **cohort, case-control, and cross-sectional studies** (combined)
- Checklist for **cohort studies**
- Checklist for **case-control studies**
- Checklist for **cross-sectional studies**

# Title and abstract

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- (a) *Indicate the study's design with a commonly used term in the title or the abstract*
- (b) *Provide in the abstract an informative and balanced summary of what was done and what was found*

# Introduction

- **Background/rationale:**
  - ▣ Explain the scientific background and rationale for the investigation being reported
- **Objectives:**
  - ▣ State specific objectives, including any pre-specified hypotheses

# Methods

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- **Study design**

- ▣ Present key elements of study design early in the paper

- **Setting**

- ▣ Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection

# Methods: participants

- **Cohort study**—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up
- **Case-control study**—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls
- **Cross-sectional study**—Give the eligibility criteria, and the sources and methods of selection of participants

# Methods: matched studies

- *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed
- *Case-control study*—For matched studies, give matching criteria and the number of controls per case

# Methods: Variables

- Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
- **Quantitative variables**
  - ▣ Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why

# Methods: Data sources/ measurement

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- For each variable of interest, give sources of data and details of methods of assessment (measurement).
- Describe comparability of assessment methods if there is more than one group

# Method: Bias & Study size

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- Describe any efforts to address potential sources of bias
- Explain how the study size was arrived at

# Method : Statistical methods

- *Describe all statistical methods, including those used to control for confounding*
- *Describe any methods used to examine subgroups and interactions*
- *Explain how missing data were addressed*
- *Cohort study—If applicable, explain how loss to follow-up was addressed*
- *Case-control study—If applicable, explain how matching of cases and controls was addressed*
- *Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy*
- *Describe any sensitivity analyses*

# Results: Participants

- Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed
- Give reasons for non-participation at each stage
- Consider use of a flow diagram

# Results: Descriptive data

- characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
- number of participants with missing data for each variable of interest
- *Cohort study—Summarise follow-up time (eg, average and total amount)*

# Results: Outcome data

- *Cohort study—Report numbers of outcome events or summary measures over time*
- *Case-control study—Report numbers in each exposure category, or summary measures of exposure*
- *Cross-sectional study—Report numbers of outcome events or summary measures*

# Main results and Other analyses

- unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
- *Report category boundaries when continuous variables were categorized*
- *If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period*
- Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

# Discussion

- **Key results:** Summarise key results with reference to study objectives
- **Limitations:** Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
- **Interpretation:** Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
- **Generalisability:** Discuss the generalisability (external validity) of the study results

## Other information

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- the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

# CASP: Cohort study

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**CRITICAL APPRAISAL SKILLS PROGRAMME**  
**making sense of evidence**

**12 questions to help you make sense of a cohort study**

# General comments

- Three broad issues need to be considered when appraising a cohort study:
  - ▣ *Are the results of the study valid?*
  - ▣ *What are the results?*
  - ▣ *Will the results help locally?*

# screening questions

- The first two questions are screening questions and can be answered quickly. If the answer to those two is "yes", it is worth proceeding with the remaining questions.
1. **Did the study address a clearly focused issue?**
  2. **Did the authors use an appropriate method to answer their question?**

# Validity: Detailed Questions

- 3. Was the cohort recruited in an acceptable way?**
- 4. Was the exposure accurately measured to minimize bias?**
- 5. Was the outcome accurately measured to minimize bias?**
- 6. Have the authors identified all important confounding factors?  
Have they taken account of the confounding factors in the design  
and/or analysis?**
- 7. Was the follow up of subjects complete enough? Was the follow  
up of subjects long enough?**

# What are the results?

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- 8. What are the results of this study?**
- 9. How precise are the results? How precise is the estimate of the risk?**
- 10. Do you believe the results?**

# Will the results help me locally?

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**11. Can the results be applied to the local population?**

**12. Do the results of this study fit with other available evidence?**

# Randomized clinical trials

# CONSORT

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- **Consolidated Standards of Reporting Trials**
- **22 items**

# HISTORY OF CONSORT

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- CONSORT (Consolidated Standards of Reporting Trials) statement (In the mid 1990s)
- The revised CONSORT statement (1999, 2000)



The CONSORT statement comprises:

a 22-item checklist **pertain to the content of**

**the Title,**

**Abstract,**

**Introduction,**

**Methods,**

**Results,**

**Comment.**

a flow diagram **depicts information from 4 stages of a trial**

**enrollment,**

**intervention allocation,**

**follow-up,**

**analysis**

# Title and abstract

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- How participants were allocated to interventions (e.g., “random allocation,” “randomized,” or “randomly assigned”).

# Introduction: Background

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- Scientific background and explanation of rationale.

# Method:

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- **Participants:** Eligibility criteria for participants and the settings and locations where the data were collected.
- **Interventions:** Precise details of the interventions intended for each group and how and when they were actually administered.
- **Objectives:** Specific objectives and hypotheses.

# Method:

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- **Outcomes:** Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).
- **Sample size:** How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.

# Method: Randomization

- **Sequence generation:** Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).
- **Allocation concealment:** Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.
- **Implementation:** Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.

# Method:

- **Blinding** (masking): Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.
- **Statistical methods:** Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.

# Results

- **Participant flow:** Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.
- **Recruitment:** Dates defining the periods of recruitment and follow-up.
- **Baseline data:** Baseline demographic and clinical characteristics of each group.

# Results

- **Numbers analyzed:** Number of participants (denominator) in each group included in each analysis and whether the analysis was by “intention to treat.” State the results in absolute numbers when feasible (e.g., 10 of 20, not 50%).
- **Outcomes and estimation:** For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval).

# Results

- **Ancillary analyses:** Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.
- **Adverse events:** All important adverse events or side effects in each intervention group

# Discussion

- **Interpretation:** Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes.
- **Generalizability:** Generalizability (external validity) of the trial findings.
- **Overall evidence:** General interpretation of the results in the context of current evidence.

## **Critical Appraisal Skills Programme (CASP)**

making sense of evidence

## **10 questions to help you make sense of randomised controlled trials**

Public Health Resource Unit, England (2006).

# Screening Questions

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- **1. Did the study ask a clearly-focused question?**
- **2. Was this a randomised controlled trial and was it appropriately so?**

# Detailed Questions

3. Were participants appropriately **allocated** to intervention and control groups?
4. Were participants, staff and study personnel '**blind**' to participants' study group?
5. Were **all** of the participants who entered the trial accounted for at its conclusion?
6. Were the participants in all groups followed up and data collected in the **same way**?
7. Did the study have **enough participants** to minimize the play of chance?
8. How are the **results** presented and what is the main result?
9. How **precise** are these results?
10. Were all important outcomes considered so the results can be **applied**?

Any questions?

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