PRACTITIONERS GUIDANCE
SERIES XVII

SCIENTIFIC WRITING

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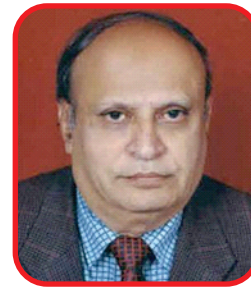

Foreword

I am very glad to write foreword to practitioner's guidance series booklet XVII. This booklet is entirely on **scientific writing.**

Scientific writing carries immense significance. It is very important for academic career of a Doctor.Only researcher need not write scientific articles. Practitioners should develop such an aptitude. Practitioners should also collect data about epidemiology of diseases, analyse and publish observational studies.

Right way to start research is by conceiving hypothesis, get clearance from ethics committee, and consider the Finances involved in the study and funding sources, and facilities available.Everyone should be kept in mind about conducting research. One should be conversant with proper writing of scientific articles. Publication will have weightage if articles are published in peer-reviewed, indexed journals.

Statistical analysis of the sample, dispersion of values, chi squire, p- value determinations, sensitivity, specificity,positive and negative predictive values are important part of research article.

Globally,Universities are graded based on publication of research papers.

Basic honesty is required for publications. Bias factors are to be kept in mind. Influence of pharmaceutical companies should be discouraged. There should not be any conflict of interests.Plagiarism is considered as a violation of academic integrity and violation of publication ethics.

I am glad that editorial committee has done a very good job for the Council by publishing practitioners series which is of immense benefit to the practitioners.

H. Veerabhadrappa
President

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Preface

Scientific writing consists of journal articles such as original research articles, review articles, case reports, letter to the editor or book reviews, or writing a chapter in a book or producing a whole book. In addition, it includes conference presentations of abstracts, oral presentation and poster presentation.

The original research must be able to answer a clear research question. It is possible to design the study the material properly and ethically. The study should not be biased. There is uniform requirement for all manuscripts submitted to biomedical journals for publication. The writing must be specific. It should be properly written with short sentences using familiar terminology. There should not be any jargon and acronyms or vague, unclear statements. It should present important and essential details. The data should be properly analysed, statistically evaluated and interpreted. While discussing the topic, it should not ignore important publications on that subject. A good research writing should fulfill FINER criteria which consist Feasible, Interesting, Novel, Ethical and Relevant.

Leading academicians have contributed to produce this book on Scientific writing. The book has been brought out to guide the youngsters to prepare their writing on a scientific way. We hope our attempt will be of some help to guide them. I express my gratitude to the contributors.

P. S. Shankar

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Guidelines for Writing a Scientific Paper

Indu Mani, Anura V Kurpad,

Introduction

Any scientific research is considered incomplete if the results of that research are not accessible to other scientists. One key reason for writing a scientific paper is to disseminate one's research findings to improve science and public health. Peer-reviewed papers improve a researcher's visibility and help to establish credibility through the quality and significance of the work. A researchers' success is measured by the quality, prestige, impact factor of journals in which the results are published, and the number of citations. Finally, and most importantly, it is essential to obtain funding for future research and for professional advancement.

Preparation of a manuscript

Writing a paper should involve as much effort and consideration as is given to the physical execution of the study. There are quite a few articles and papers written about how to write an effective scientific paper, however many young scientists do find it an intimidating task.

First of all, when is it time to write a manuscript? The following points can be kept in mind prior to writing the paper:

1. Has a significant advancement been made?
2. Did the study confirm/reject the hypothesis?
3. Can the key message or findings be written in 1 or 2 sentences?
4. Is this paper novel, important, comprehensible, informative, useful, and ethical?
5. Does it break new ground or resolve major controversy?

Types of Scientific writing

There are different types of papers that can be written (*see* text box) . In general, a scientific paper follows the general pattern of – Title, Abstract, Introduction, Materials and Methods, Results and Discussion, Conclusion, and finally the References.

Types of scientific writing

1. Original research papers
2. Case report/case series
3. Quantitative review
4. Review article/ chapter
5. Editorial/Commentary
6. Letters to the editor/short communication

Title

The title should be substantially indicative of the work. It is preferable to avoid long titles as well as abbreviations

Abstract

An abstract is a concise summary of the entire paper, usually about 250-300 words long, containing all the keywords (for online retrieval). The abstract is very important since it lets the reader decide if the rest of the paper is worth a detailed reading. The abstract is written in the 3rd person and should briefly describe the problem addressed by the paper, the methods used to solve the problem, the results obtained and the authors' conclusions. This is usually written after the entire paper is completed.

Introduction

The introduction defines and introduces the problem investigated. Previous research and studies are quoted to assure the reader of the necessity of the current work. This section

(i) give the significance of the topic with emphasis on the specific question addressed by the experiments,

(ii) describe the information gap in literature, hence the importance of the present study,

(iii) briefly describe the approach taken in the study, and

(iv) mention the results and the subsequent development of a hypothesis.

The introduction is not an exhaustive review of literature, and some of the pitfalls to avoid include unclear objectives, confusing structure, too many citations and first-person anecdotes.

Materials and Methods

The Materials and Methods section should provide a clear and concise description of the procedures used in the paper. It should include sufficient details of the techniques such that another person in the field can actually reproduce it. Details of published protocols can be cited (e.g. was done by the method of . . .). However, any changes to the published protocol should be clearly mentioned.

The Methods section should be written in the past tense with descriptive subheadings. It should start with a paragraph on the overall study design, followed by detailed description of the type of population selected (either animal studies, human studies or cell culture studies). The details of the protocols used in the study and the outcomes that were measured should be outlined, and finally the statistical tools used for analysis of the data should be described.

In the case of human and animal studies, it is now essential to include the documentation of ethical approval.

Results

The results section should be a factual representation of the outcomes of each experiment. The complete description of the study population should be included (accrual, refusals, reasons for drop-outs etc). Focus on the primary findings, but also present secondary end points. Present the data in a logical (not necessarily historical) order.

The results can be represented as figures, tables or graphs, and should be summarized in the accompanying text. References to a particular table or figure should be capitalized (e.g., Table 1, Figure 6, etc.). Tables and figures should essentially be self-explanatory even without having to read the accompanying text. Non-significant findings need to be reported as well.

Simple conclusions of the results can be included, but further explanations or justification of the data should be dealt with only in the discussion section.

Discussion

The discussion cannot be simply a repeat of the results section. It is essential to summarize results with your interpretations and conclusions. The findings need to be contextualized in view of broader literature and compared to previous research. Reasons for

similar or divergent results need to be convincingly presented, for e.g. use of a different method, a different model, etc.

One should discuss both significant as well as non-significant results, since it helps to convince the reader that the final conclusions are not biased or one-sided. In all cases, the discussion should include comparisons to previously published data, with the necessary explanations for both similar as well as contradictory results.

Some key pitfalls to avoid include repetition of results, introduction of new results, broad statements and incorrect interpretation of inconclusive results, exaggeration of findings and also extensive criticism of other authors or previous research

Conclusion

The conclusion should be a concise short paragraph of not more than 3-4 sentences. This cannot be a repetition of the results or the discussion, but a carefully worded interpretation of your data, with a final hypothesis that you would like to claim. Speculative claims can be made with a rider that further studies are required to confirm the hypothesis.

References

No paper is complete without giving credit to other authors whose work has shaped your own paper. There are a variety of ways of citing references in the text depending on the policy of the journal. The ways the references are mentioned in the text are also different for different journals.

Acknowledgements:

Acknowledge substantial help from study population, staff, laboratory personnel, funding agency and individuals who contributed but are not co-authors.

General comments

These are the things to keep in mind when writing a manuscript:

1. The writing should be clear, concise and logical.
2. It should meet formatting guidelines of the journal of interest
3. The text should be in active voice - avoid first person
4. The subjects should be close to verbs. Importance should

be given to grammatical accuracy, especially to correct spelling

5. Long sentences should be split and the first and last sentence of each paragraph should be checked to assure emphasis, transitions and flow.

General comments

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4. The subjects should be close to verbs. Importance should be given to grammatical accuracy, especially to correct spelling
5. Long sentences should be split and the first and last sentence of each paragraph should be checked to assure emphasis, transitions and flow.
6. Finally, one should read the text aloud and ask others to read the paper.

Structure of a Scientific Manuscript: How to write Title, introduction, subjects and methods, results, discussion, conclusion and References

Anura V Kurpad

Why to publish?

Dissemination of research findings to improve science and public health

- Visibility: peer reviewed scientific literature
- Credibility: quality, timeliness, and significance
- Measures of Success: quality, prestige, impact factor, number of citations,
- immediacy index
- Funding, professional advancement

Has a significant advancement been made?

- Did the study confirm/reject the hypothesis?
- Can you describe the study in 1 or 2 minutes?
- Can the key message or findings be written in 1 or 2 sentences?
- Is this paper novel, important, comprehensible, informative, useful,
- and ethical?
- Does it break new ground or resolvemajor controversy?
- Is it time to write the manuscript?

What constitutes a good science?

Novel

§ Novel ~= important

§ Clinically relevant

Mechanistic

§ Testing a hypothesis

Determining the fundamental processes involved an action, reaction, or other

Natural phenomenon
Descriptive
§ Describes how things are but does not test how things work
–
Hypotheses are not tested

Types of scientific writing

Original research papers

- Case report/case series
- Quantitative review
- Review article/ chapter
- Editorial/Commentary
- Letters to the editor/short communications

It's easier to embalm the dead than to write an article about it."

Paul Silvia

Barriers to writing

In the typical academic setting, **external barriers** to writing include:

§ clinical work,
§ teaching responsibilities,
§ committee assignments,
§ other personal time occupying Responsibilities

Intrinsic barriers to writing include

§ the inability to begin, sustain, or complete "A manuscript, which share similar roots with procrastination, perfectionism, or insecurity" (1)

Typical structure of a manuscript

Title

- Abstract
- Introduction
- Methods and Materials
- Results
- Discussion and
- Conclusions
- Acknowledgements
- References
- Tables and Figures

How to write your first research paper (2)

Schedule your writing time

- Outline
- Start with methods
- Results, then
- Introduction, then
- Discussion, then
- title

A Scientific paper is really 3 separate papers

Technical: Exciting the attention

Title:

Abstract: Should be readable by anyone

The whole paper is technical

Title

It should be substantially indicative of the content

§ Keywords

Title format(journal guidelines)

§ Avoid long title

§ Avoid abbreviations

"Running head": a brief title (45 to 60 characters)

Bad and Good titles

- "Some disease prevalence in Bengaluru"
- Student behavior in class
- Should truly reflect purpose and findings of study
- Not too long
- Watch abbreviations
- Exciting

"Neighborhood SES in relation to dietary intake and insulin resistance

syndrome in female medical students from Davangere"

Word Choice

"Short words are best, and old
words, when short, are best of all"

Winston Churchill

Writing Style

- Clear, concise, logical writing
- Meet formatting guidelines
- Active voice, avoid first person

- Subjects should be close to verbs
- Grammatical accuracy, correct spelling
- Split long sentences
- Check the first and last sentence of each paragraph to assure
- emphasis, transitions, flow
- Read the text aloud, ask others to read paper

Be precise

"A PhD student wrote that he

measured basal metabolic rate (BMR) when all he did was read

BMR from the BIA machine calculation"

Omit needless words

Vigorous writing is concise. A sentence should contain no unnecessary words, a paragraph no unnecessary sentences, for the same reason that a drawing should have no unnecessary lines and a machine no unnecessary parts...theexpression*thefactthatshouldberevisedoutofeverysentencei nwhich it occurs.*

- *owing to the fact that since (because)*
- in spite of the fact that though (although)
- I was unaware of the fact that I was unaware that (did
- not know)

Exampes: Words and Expressions

To Avoid Jargon (avoid)	Preferred Alternative
A considerable amount of	**much,**
on account of	**because, due to**
a number of	**several**
referred to as	**called**
employ has the capacity to	**use**
is clear that clearly	**can**
	clearly

Abstract

Clear and concise

- Contain all keywords (online retrieval)
- Critical part of paper
- Summarize major conclusions and significance
- Adhere to journal format (200---300 words)
  - § e.g., Background, Objective, Methods, Results, Conclusion
- Recheck abstract numbers with text
- Write last but one submitted first (conference)

- *Background:* Many sub-Saharan Africa countries with a high burden of TB also have a high rate of HIV/AIDS. Children are thought to contribute 15 - 20% of the TB disease burden in these populations.

Methods: HIV-infected children under age 15 years were enrolled in the Tanzania/President's Emergency Plan for AIDS Relief (PEPFAR) program between November 2004 and September 2011. Cox hazard regression was used to explore the predictors of incident TB after enrollment. Incident TB cases were defined as children who were prescribed anti-TB medications during follow-up who were not previously diagnosed with TB.

Results: 5114 children (median age: 5 years, IQR: 2-9 years) were enrolled in the program; 49% were male. During a median follow-up of 0.(interquartile range [IQR]: 0.1-2.4) years, 450 out of 5114 children met the case definition for TB. The overall incidence of TB was 62/1000 person-years. In multivariate analyses, older age at enrollment (RR: 1.79, 95% CI: 1.61-1.98), severe wasting (RR: 2.10, 95% CI: 1.57 -2.79), severe immune-suppression (RR: 2.63, 95% CI: 1.88-3.69), severe anemia (<7.0 g/dl) (RR: 2.88, 95% CI: 1.84-4.52) and advanced WHO stage (RR: 4.67, 95% CI: 2.42- 8.98) were independently associated with a higher risk of TB. In addition, the use of highly-active antiretroviral therapy (HAART) reduced the risk of TB by 26% (RR: 0.74, 95% CI: 0.58-0.96).

Conclusions: HIV-infected children in Tanzania have a high rate of TB infection. Wasting, immune suppression, anemia and advanced WHO clinical stage are key independent risk factors; HAART significantly reduced the risk of developing TB. Nutritional supplementations to prevent wasting and anemia, as well as HAART, should be included in HIV care and treatment program to reduce the burden of childhood TB. Duggan et al

Include description of analysis approach:

OBJECTIVE:

To examine pretreatment factors associated with longer term (144---week) responses to an-retroviral therapy (ART).

METHODS:

Of 1498 ART---naïve subjects randomized to ART regimens, including > or =3 agents, 1083 patients who had plasma HIV RNA (vRNA) levels and CD4 cell counts at baseline and week 144 were analyzed. Primary baseline factors evaluated were CD4 cell count, vRNA level, sex, race, and age, using multivariable Cox, log--binomial, and linear regression models.

RESULTS:

Shorter time to achieving a vRNA level <50 copies/mL was associated with lower baseline vRNA level (P < 0.001) and older age (P =0.007)

- Pitfalls to avoid
  - § Too detailed (particularly background, methods)
  - § Conclusions too broad

Introduction

- Define and introduce problem investigated
- Previous research
- Define knowledge gap
- Statement of problem, central research question
- Rationale, equipoise
- Describe main objective of paper (last paragraph)

Pitfalls to avoid

- § Excess detail in background
- § Unclear objectives
- § Confusing structure
- § Too many citations (cite minimum necessary)
- § First---person anecdotes

Introduction should narrow down from

- General problem
- What is known and not known
- What was the idea here
- Objective

Methods and materials

- distillation of the protocol
- clear and concise description of how study was conducted
- past tense, descriptive subheadings (journal requirements)

Provide enough detail so that the study can be replicated by others

§ Studydesign
§ Study population: recruitment, IRB approval
§ Setting
§ Data collection procedures
§ Interventions
§ Define main exposure and outcome
§ Data analysis, statisticalmethods

Data analysis, statistical methods:

§ Include the steps needed to replicate the presented results from the raw data
§ e.g., baseline is the average of pre---entry & entry
§ Data transformations (e.g., log10)
§ List the variables evaluated
§ Specify the statistical analysis methods
§ Consider including a reference for any non--- standard (or less well known) statistical procedures

Results

Describe study population (accrual, refusal, dropouts)

- Consort statement
- Focus on primary findings; present secondary endpoints
- Clear presentation, definition of variables
- Logical (not necessarily historical) order
- Refer to tables and figures (no replication)
- Present non-significant findings too
- Give estimates and confidence intervals
- Structure of presentation
- For example, open a paragraph with simple descriptive sentence, including simple summary statistics
- Then, proceed to results obtained from statistical modeling
- Tell a story with the results

Two-year mortality was lower in those starting regimen A *vs* B: 19/101)19%) *vs* 29/99(29%) death. The unadjusted hazards rates (HR) was 0.69 (95% CI; 044-0.95, p=0.035). This difference was attenuated after adjusting for pre-treatment CD4 count and age (HR=0.75, 95% CI:..

Results

Pitfalls to avoid

- Reporting of methods
- Discussion of results, interpretation of data
- Redundancy-repetition of figures and tables

Discussion

Summarize results-What are the key findings?
Interpretation of results

- Confirm/deny the hypothesis?
- Assess the validity of the present work
- Evaluate evidence re research question

Contextualize findings in the broader literature

- Compare to previous research
- Contribution to knowledge base
- How does this study address groups in literature?

Strengths

- Significance of the results
- Novelty? Contributions to groups

Limitations

- Non-response, drop-out. Measurement error, study design limitations
- Missing or inadequately measures/controlled for variables (cofounding, residual confounding)

Generalizability of findings?
Implications for clinical care, research, policy, programs?
Suggestions for future research

Pitfalls to avoid

- Repetition of results, introduction of new results
- Broad statements
- Incorrect interpretations of inconclusive results
- Exaggeration of findings
- Extensive criticism of other authority or previous research Discussion should broaden out
- Interpretation of the data, with respect to the objectives of the study
- Get progressively broaden, external validity, interpreting papers by others
- End with the broad problems and concept in the start of the introduction

Tables and figures

- Tables: present lists of numbers/text

- Figures: visual representation of results or illustration of concepts/methods (graphs, diagrams_
- Tables and figures should be developed to be stand-alone summaries
- Clear, easy to understand for expert and non-expert audiences
- Interpretation to someone unfamiliar with your study or findings
- Complementary and consistent with narrative
- Select the most important findings

Guidelines:

- Demonstrate main findings
- Clearly define abbreviations and terms
- High resolution
- Simple
- Standards

References

- Relevant and recent
- Highly selective-value of review articles
- Use correct style for journal
- Reference peer-reviewed journal, articles, abstracts, books
- Should not refer non-peer reviewed works, personal communications
- Verify each reference as cited correctly (spelling)
- Verify each reference is complete

Pitfalls to avoid

- Formatting
- Redundant information
- Too many (be selective)
- Balanced references (avoid too many from the same group)

Acknowledgements

- Active substantial help from study population
- Sites, staff, laboratory personnel
- Funding agency (grants)
- Individuals who contributed but are not coauthors (permission sometimes needed)
- Relevant institutions for guidance

References

1. El--Serag HB. Writing and publishing scientific papers. Gastroenterol2012; 142: 197--□200
2. Kallestinova, ED. How to write your first research paper. Yale J Biology and Medicine, 2011;84:181–190

Ethics Committee

G. D. Ravindran

Introduction

In the late forties, the first randomized trials were conducted in the world. The Patulin trial in 1943 and the Streptomycin treatment of Pulmonary Tuberculosis in 1948 were the earliest trials conducted in the world. Both the trials were conducted by Medical Research Council (MRC). Sir Austin Bradford Hill is credited for organizing the Streptomycin trial. He used the Hippocratic Oath as the basis for conducting the study. There were no ethics committees at that time. He obtained consent from the participants. When participants interviewed, they participated in the trial because they believed that they were helping to discover a treatment for Tuberculosis and they trusted their doctors.

Early part of clinical trials was dominated with altruism and trust between the investigators and the subjects of research. The patients believed that their participation will contribute to improved health for others and that researchers will minimize risks to participants. As the randomized clinical trial (RCT) became the golden standard for the use of drugs, the simple relationship between the doctor and patient changed.

In the same year (1948) the atrocities of the Nazi rulers led to the Nuremberg Declaration. In 1964 Helsinki declaration was published. In the sixties, Beecher published unethical trials that were being conducted in the United States. The Tuskegee study in 1970 brought out the vulnerabilities of the research subjects. All these events lead to development of the Belmont report in 1974. It was essential to protect the subject. Hence, ethics committees (ECs) were set up protect the subjects.

Doctor – Patient relationships

The patient suffers from his disease. The physician has the technical knowledge and specialized knowledge to help the patient from his ailment. The relationship between the doctor and the

patient is an unequal relationship. The physician has upper hand in this relationship and he can exploit the patient. In a research setting the subject may get the best care. He may benefit from the new treatment. At the same time, he is exposed to risk associated with the side effects of the drugs. The physician gains by adding knowledge and the fame that goes with the scientific activities. He may also benefit financially. He does not undertake any risk. An unscrupulous physician can exploit the patients to his advantage. The interest of the subject has to be protected. This is achieved if there is a mechanism to protect the interest of the research subjects. Hence, there is a need for ethics committees.

Ethics committee Work

Ethics committees (ECs) have tremendous responsibilities. They have to examine the protocol to see whether the proposed methodology is scientific and if it can answer the question that it has raised. The proposal should be scientifically sound and clinically meaningful. Ethics committees have to see that there is clinical equipoise before the study is started. Clinical equipoise means that there is no difference in the outcomes between two groups of patients at the start of the study. As data accumulates, there may be a difference between two groups and if it is significant then the trial is stopped.

Apart from the scientific review the ethics committee also has a duty to protect the trial participants. It has to make sure that there is no exploitation of the patient; proper consent is obtained as well as the risks are equally disturbed

The ethics committee is mandated to supervise the research and to see that it is conducted according to the protocol. It has a right to examine the data and results. It also has to advise the researcher on different aspects of the trial, so that the investigation becomes scientifically and ethically sound. Scientific review precedes the ethical review. For proper review, the ethics committee can request experts in the field to review the scientific part of the proposal.

Composition of Ethics committee

The hallmarks of the ethics committee are its independence and it should be competent. The ethics committees should be constituted by the authority of the institution or board. The ECs should specify in writing the authority under which the Committee was established. The composition of the ethics committee should be

multidisciplinary and multi-sectorial. The number of persons in an ethics committee should be kept fairly small (8 - 12 members).A minimum of five persons is required to form the quorum without which a decision regarding the research should not be taken.

The board that constitutes the ethics committee has to appoint members to the ethics committee. The appointment must be for a specified period. The term of appointment of members can be extended for another term. A defined percentage of members have to be changed on regular basis. The members should undergo regular training in ethics. The EC can nominate a substitute member only when a regular member does not attend the specified number of meetings continuously due to some unforeseen circumstance.

The ethics committee must have standard operating procedure(SOP) that is written down even before the committee starts its function. The SOP must include all the details of the members.

The composition of Ethics committee: Ethics committee comprises of the following members

1. One - two persons from basic medical science area
2. One - two clinicians from various Institutes
3. One legal expert or retired judge
4. One social scientist/ representative of non-governmental voluntary agency
5. One philosopher/ ethicist/ theologian
6. One lay person from the community

The chairperson of the committee should be appointed by the appointing authority. He/She should not be from the institution. The head of the institution should not be the chairperson. These precautions are taken to ensure independence of the committee. The Member Secretary of the committee should be from the institution so that the business of the committee can be conducted smoothly.

The ethics committee should be constituted by an appropriate authority i.e. the management of the hospital. The terms of reference should include the names of the members and the duration of their terms.

Each ethics committee must have standard operating procedures that states how it will function. It should have a policy for removal/replacement of members and the resignation procedures if

the members want to resign. It should state the frequency of meetings. The charges that are levied for review should be specified. The honorarium that will be paid for the consultants/ experts and members must be mentioned.

Review Procedures

The proposals have to be submitted to the member secretary or to ethics committee office. The last date for submission should be at least one week before the scheduled meeting of the EC. The EC's member-secretary or secretariat shall screen the proposals for their completeness and depending on the risk involved categorize them into three types,

1. Exemption from review
2. Expedited review
3. Full review

Accordingly, the review will be undertaken by the ethics committee.

The risk of the study to the participants in the research has to be decided by the chairperson/ member secretary of the committee. The studies that involve minimal risk are defined as 'An intervention which may be anticipated as harm or **discomfort not greater than that encountered in routine daily life activities** of general population or during the performance of routine physical or psychological examinations or tests.'

Decision making process

The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. A brief summary of the project with informed consent and patient information sheet, advertisements or brochures, should be circulated to all the other members. The ethical review should be done in formal meetings and EC should not take decisions through circulation of proposals. The committee should meet at regular intervals. It should not keep a decision pending for more than 3 - 6 months.

The Member- Secretary should communicate the decision in writing to the principal investigator (PI). All the discussions of the EC should be documented. A negative decision should always be supported by clearly defined reason and conveyed to the PI. EC can reverse its decision.

Review process

The EC also has a duty to review the research that is being carried by the PI. The EC has the responsibility to continue reviewing approved projects for continuation, new information, adverse event monitoring, follow-up and later after completion if need be.

Monitoring

Apart from reviewing, IEC has a responsibility to monitor the study. It also has to monitor adverse reactions. In case the IEC desires so, reports of monitoring done by the sponsor and the recommendations of the Data and Safety Monitoring Board (DSMB) may also be sought.

Record keeping

All documentation and communication of an IEC are to be dated, filed and preserved according to written procedures. Strict confidentiality is to be maintained during access and retrieval of the documents. It is recommended that all records must be safely maintained after the completion/termination of the study for a period of 3 years

Protocol and its relevance to the guiding principles

The protocol that is submitted to the ethics committee should answer the ethical principles that have been outlined above. Introduction and review of the literature section of the protocol helps the EC to determine if the research is essential. Aims and objectives of the study help to clarify this issue. Informed consent form that is submitted to the EC will help the EC to decide if the principles of informed consent and voluntariness are followed.

The materials and method section will help the EC to decide if the research question is being answered. The subject selection, inclusion and exclusion criteria will help the EC to determine if the research is non-exploitative. The material methods section must mention the ways and means of protecting confidentiality of the subjects. The protocol must clearly the ways and duration the records will be preserved. This will ensure that privacy and confidentiality will be preserved. The methods section must also indicate how public interest and distributive justice will be carried out. Methods section will also indicate the precautions that the investigator will adopt to reduce the risks.

Curriculum Vitae of the principal investigator and of the co-investigators will help the EC to decide if the investigators are competent to conduct research. Similarly, disclosure of conflict of interest is essential.

It is essential that all institutional and financial arrangements are informed in the protocol. The protocol must clarify the responsibility and role of the funding agency, the institution and the research so that the accountability can be identified. The protocol must indicate a section on how the results will be disseminated. This will help the EC to determine if the material will be available in the public domain.

By regularly monitoring the research by interim reports regular reviews, audit and with the final report, the EC will be able to monitor that the researcher is compliant with the protocol that has been approved.

Conclusion

Ethics committee has a great responsibility to protect the research participant and the science. EC has a primary obligation to protect the patient. The PI has a duty to supply all the necessary details to the EC, so that the EC can make a correct decision. EC also has a duty to help the PI to improve the study so that together they can contribute to development of knowledge.

Original research paper

Sudarshan MK

Introduction

A research paper is a scholarly article that contains the results of original research or an evaluation of research conducted by others. There are various types of research paper assignments that aim to help the researcher understand different concepts, while building creative thinking and writing abilities.For a good understanding and developing writing skills, the following are just a brief mention of different types of research papers that are written.

I. Types of Research Paper

1. **Academic paper**: (also called scholarly paper)It is published in academic journals and contains original research results or reviews existing results.
2. **Term paper:**It is a written original work discussing a topic in detail, written usually by high school or college students, often due at the end of a semester and accounting for a large part of grade.
3. **Thesis or dissertation:** It is a document submitted in support of a candidature for a degree or professional qualification, presenting the author's research and findings.

II. Structure of an original research paper

The **IMRAD**refers to the standard structure of the body of scientific paper (after the title and abstract) of original research work. *IMRAD* is an acronym for **i**ntroduction, **m**ethods, **r**esults, **a**nd **d**iscussion.

- **Introduction** - Why was the study undertaken? What was the research question, the tested hypothesis or the purpose of the research?
- **Methods** - When, where, and how was the study done? What materials were used or who was included in the study groups (patients, etc.)?

- **Results** - What answer was found to the research question; what did the study find? Was the tested hypothesis true?
- **and**
- **Discussion** - What might the answer imply and why does it matter? How does it fit in with what other researchers have found? What are the perspectives for future research?

This standard structure gives a logical flow to the content, makes journal manuscripts predictable and easy to read, provides a 'map' so that readers can quickly find content of interest in any manuscript and reminds authors what content should be included.

The IMRAD format has been adopted by a steadily increasing number of academic journals since the first half of the 20th century. Many scientific journals now not only prefer this structure but also use the IMRAD acronym as an instructional device in the instructions to their authors, recommending the use of the four terms as main headings. For example, it is explicitly recommended in the "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" issued by the International Committee of Medical Journal Editors (previously called the Vancouver guidelines).

III.Choosing a target journal

Submitting a manuscript to an unsuitable journal is a common mistake, and consequently journal editors reject the manuscript without even sending it for peer review. Hence, choosing a right journal that matches your study is very important because it makes your manuscript to be more likely accepted. Some factors to consider about the target journal are:

- The **topics** the journal publishes. If your research is applied, you should choose a journal that publishes applied science; if it is clinical, you should target a clinical journal; if it is basic research, you should choose a journal that publishes basic research. You may find it easy to browse a list of journals by subject area.
- The journal's **target audience**. If you think researchers in other fields will be interested in your study, a journal that covers a broad range of topics may be best. On the other hand, if only researchers in your field are likely to want to read your study, then a field-specific journal would be best.
- The **types of articles** the journal publishes. For example, if you want to publish a *Review Article*, find out whether the

journal publishes these. If you wish to present a *case study*, ensure that the journal you are targeting actually publishes the type of manuscript you wish to submit.

- **Length restrictions**. Does the journal limit the number of words in the articles it publishes? Can your manuscript meet its requirements? However, some journals may not have any such restrictions *per se*.
- The **reputation** of the journal. A journal's Impact Factor is only one measure of its reputation, but not always the most important. It is important to find out the details of indexing of the journal as a measure of standard and value addition. You need to consider the prestige of the authors that publish in the journal, and the size of the journal's readership. Objectively consider how important your research is and what level of journal it is best suited for like national or international, etc.; otherwise, you may be wasting your valuable time submitting to one journal after another. Other factors to consider: Does the journal usually publish articles quickly; is the "time to publication" important for you? Would you prefer an *open access journal* that might give much greater exposure to a wider audience? What are the processing/publication fees? And whether it is affordable?

Thus it is very important togive a serious thought about choosing the target journal before you start writing your manuscript. When looking for suitable journals in which to publish your own results, *start with what you have read*. You should already be familiar with published studies that are similar to yours. Which journal were those studies published in? The same journals may be appropriate for your manuscript, so make a list of them. If you need more journals to consider, you can do literature searches for other published articles in your field that are similar in scope and impact on the field, and see where they were published.

When you have a list of potential target journals, *visit and read the websites of these journals*. Every journal should have a page that provides instructions for authors, including information on many of the factors listed above.

If you are in a hurry to publish, consider which journal offers rapid publication; if none do, consider which has the highest publication frequency. If your main goal is to reach as many readers as possible, strongly consider candidate journals that provide an open access option. Open access allows anyone to read your article, free of charge, online, which can make your article more likely to be read and cited.

When you have chosen the journal you think is the best fit for your study and your goals, it is usually a good idea to also identify your second- and third-choice journals. That way, if your paper is rejected from your first-choice journal, you can quickly submit to your second-choice journal and so on.

IV. Peer Review

The Peer review is a positive process. Peer review is an integral part of scientific publishing that confirms the validity of the science reported. Peer reviewers are experts who volunteer their time to help improve the journal manuscripts they review and mostly they offer authors free advice. Peer review exists to ensure that journals publish good science. This benefits the entire scientific community. Sometimes scientists find the peer review process intimidating because it can lead to the rejection of their manuscript but it must be kept in mind that revisions and improvement are part of the publication process and actually help raise the quality of your manuscript. Through the peer review process, manuscripts become:

More robust: Peer reviewers may point out gaps in your paper that require more explanation or additional experiments.

Easier to read: If parts of your paper are difficult to understand, reviewers can tell you so that you can fix them.

More useful: Peer reviewers also consider the importance of your paper to others in your field.

Of course, in addition to offeringadvice to authors, another important purpose of peer review is to make sure that the manuscripts the journal eventually publishes are of high quality. If a journal publishes too many low-quality manuscripts, its reputation and number of readers will decline.

Hence, Peer review is the critical assessment of manuscripts submitted to journals by experts who are usually not part of the editorial staff. Because unbiased, independent, critical assessment is an intrinsic part of all scholarly work, including scientific research, peer review is an important extension of the scientific process.More practically; it helps editors decide which manuscripts are suitable for their journals. Peer review often helps authors and editors improve the quality of reporting.

It is the responsibility of the journal to ensure that systems are in place for selection of appropriate reviewers. It is the responsibility of the editor to ensure that reviewers have access to all materials that may be relevant to the evaluation of the manuscript,

including supplementary material for e-only publication, and to ensure that reviewer comments are properly assessed and interpreted in the context of their declared conflicts of interest.The editor of a journal is ultimately responsible for the selection of all its content and editorial decisions may be influenced by issues unrelated to the quality of a manuscript, such as suitability for the journal. An editor can reject any article at any time before publication, including after acceptance if concerns arise about the integrity of the work.

Journals may differ in the number and kinds of manuscripts they send for review, the number and types of reviewers they seek for each manuscript, whether the review process is open or blinded, and other aspects of the review process. For this reason and as a service to authors, some journals publish a description of their peer-review process.

Journals should notify reviewers of the ultimate decision to accept or reject a paper, and should acknowledge the contribution of peer reviewers to their journal. Editors are encouraged to share reviewers' comments with co-reviewers of the same paper, so that reviewers can learn from each other in the review process.

V.Recommendation

The author recommends that faculty particularly those of the cadres of Assistant Professor and Associate Professor enrol for a free certified online course on "writing in science" conducted by Stanford University,USA .This course enables scientists to become more effective writers, using practical examples and exercises. The Topics of the course include - principles of good writing, tricks for writing faster and with less anxiety, the format of a scientific manuscript, and issues in publication and peer review. On successful completion of the course a certificate is issued free of cost to the learner. For more details of the course and for free enrolment visit the web link - *online.stanford.edu/course/**writing**-in-the-**sciences***

VI. References and suggested further learning.

1. International Committee of Medical Journal Editors. For guidelines on how to prepare a manuscript and submit for publication visit the web link www.icmje.org/.../manuscript-preparation/preparing-for-submission.html
2. Springer Author Academy. How to write and submit a journal article. Visit the web link http://www.springer.com/gp/authors-editors/author-academy

Abstract Writing

Cecil Ross

The title of your abstract might be all your reader ever reads.
At the very least, it determines whether the reader will read on.

Preparing abstracts

In order to prepare an effective and successful abstract, you need to understand the required structure, know how to deliver it effectively and follow certain tools and techniques along the way to make your abstract clear and concise. This write up will give you all the information that you need.

Why prepare an abstract?

An abstract is an essential tool within the medical community for communicating your work to a wider audience.

Look at all things an abstract can do

- It summarizes and differentiates your work
- It shares your work
- It is a route to gain funding and prestige for your work
- It entices readers to see your full poster/oral presentation in the scientific meeting
- It invites discussion, opinion and sharing of similar research
- Enhances your reputation within the medical community

Golden rules while preparing abstracts

Structure to follow: IMRaD (Introduction, Methods, Results and Discussion)

Before you begin to write an abstract, ask yourself a few things

- What do I want to achieve?
- What do I want to say?
- What is my audience?

Have the answers to these questions in your mind as you prepare your abstract.

When preparing your abstract, you need to use the **IMRaD** structure. Follow these simple steps and you are on your way to preparing an abstract that gets accepted to a scientific meeting.

Introduction

Aim: To give a clear understanding of why the research was performed and what question(s) this research is addressing.

How many? **2** sentences:

- 1: background to the study/ disease area
- 1: the research question (study objective)

Tips Keep to the key points

- ❖ Put your research into context for the reader
- ❖ Keep it short
- ❖ Keep it clear

Methods

Aim To inform the reader exactly what you did to address the research question(s)

- ❖ ***How many?***
  3-4 sentences

Tips

- ❖ Include study design, patient population, selection criteria
- ❖ Exclude standard methodology
  (e.g., age and gender were determined by questionnaire), and standard statistical methods
- ❖ Leave out anything totally routine; include anything different

Results

Aim

To relay what you found in your research.

How many?

- ❖ **2-3** sentences
- ❖ Include a table if appropriate

Tips

- ❖ Include primary end-point result(s)
- ❖ Emphasize the main finding(s) of the study
- ❖ Use confidence intervals /p-values
- ❖ If in doubt of what to include, go back to your research question

Discussion

Aim

To inform the reader exactly what you did to address the research question(s)

- ❖ ***How many?***
  3-4 sentences

Tips

- ❖ Include study design, patient population, selection criteria
- ❖ Exclude standard methodology
  (e.g., age and gender were determined by questionnaire), and standard statistical methods
- ❖ Leave out anything totally routine; include anything

Topic	If your topic is fascinating to you but not to others, or if your topic is similar to others at the same meeting, your abstract is far less likely to be accepted.
Poor Communication of research question	Remember to answer the research question (that you posed in the second sentence of your abstract) within your results section.
Small number of patients	If patient numbers in your research are small but you feel your topic is of interest or scientific importance, see if you can pool data with another unit.
All talk, no numbers	You must include some statistical analysis
All numbers, no talk	But not too many statistics!
Too many p-values (10 or 20 or more)	And definitely not too many p-values.
Too short/too long	Keep to the required word count often 250
"Results will be discussed" /"Data will be presented"	This does not help the reviewersknow if your abstract is of interest to participants
Too many abbreviations	This makes your abstract hard to read and so it becomes less interesting.
Errors	Abstracts with grammatical, spelling and statistical errors will be rejected.

Basics of Statistics for the Clinician

Cecil Ross, SanjuktaRao, Delon D'souza

"The problem of statistical errors in the medical literature is long-standing, wide-spread, potentially serious, relatively unknown, and not well addressed, despite the fact that most errors occur in the more common applications of statistics."

Review

This review of Basics of statistics will provide a concise approach of common statistical tests that are important from understanding the terms encountered in the medical literature.

Science is a measurement. Thus, the "who, what, when, where, and why" of the measurements must be clearly stated and appropriate for the study. Assuming that you know how something was measured is a common error. Was mucous discharge measured as present or absent? Or measured as absent, mild, moderate, or severe? Or measured as indicated on a scale of 0 to 100? Was its presence determined by patient's self-report, physical examination, or tissue counts? When you read any journal or try to embark on a study these types of questions should come to mind.

Data

As it can be seen, there are 3 types of data Nominal, ordinal and interval.

Nominal data: In a Nominal data there are named categories. There is no implied order .eg Male =1 Female =2 or Single, Married, Widow, or Separated.

Ordinal data: In ordinal type the data is the same as nominal but with order eg Stage 1, stage 2, stage 3 stage 4. or Improved, Same. Worse. Dead

Interval data: In interval data, the data are numerical The data is same as above but with equal intervals; The Zero point is arbitrary eg IQ. If Zero is fixed it is Ratio. eg Height, Weight, Age, etc.

Depending on the type of data, and the experiment, the statistical test can be chosen (Table 1)

Measure-ment	2 treatment groups of different patients	> 3 treatment groups of different patients	Before and after treatment in the same patient	Multiple treatment in the same patients	Association between 2 variables
Interval	Unpaired	ANOVA	Paired t test	Repeated measure ANOVA	Linear regression & Pearson's correlation
Nominal	Chi square	Chi square	Mc Namara's test	Cochrane Q	Contingency coefficients
Ordinal	Mann –Whitney Rank Sum Test	Kruskal Wallis Statistic	Wilcoxon signed ranked test	Friedman's statistic	Spearman rank correlation

Distribution

It is important to understand shape of the distribution. Typically, a researcher is interested in how well the distribution can be approximated by the normal distribution. Simple descriptive statistics can provide some information relevant to this issue. For example, in a study if we have checked Hb, MCV and FEP in 10,000 people, Fig 1 shows the distribution. The HB is normally distributed while the FEP is not normally distributed. It is skewed to left. if the *skewness* (which measures the deviation of the distribution from symmetry) is clearly different from 0, then that distribution is asymmetrical, while normal distributions are perfectly symmetrical. In samples that follow a "normal" distribution (ie, Gaussian), 68 and 95 percent of values fall within one and two standard deviations of the mean, respectively. (Fig 1) All statistics should be done on normally distributed data to be meaningful. If the *kurtosis* (which measures "peachiness" of the distribution) is clearly different from 0, then the distribution is either flatter or more peaked than normal; the kurtosis of the normal distribution is 0. Emerson and Colditz reviewed 760 articles in *The New England Journal of Medicine*. A working knowledge of only 3 tests 1) *1. t*-tests, 2) The Mann-Whitney *U* test and 3) [chi]2 tests are critical. This would give the reader “complete statistical access” to 75% of the articles

In a t test the data is arranged as follows.

	BP before Rx	BP after Rx
case 1	111.9	113
case 2	**109**	110
case 3	143	144
case 4	101	102
case 5	80	80.9
...	...	...
	average change between BP "before" and "after" = 1	

The Mann-Whitney U test

The Mann-Whitney test is used in experiments in which there are two conditions and different subjects have been used in each condition, but the assumptions of parametric tests are not tenable. For example, a psychologist might be interested in the depressant effects of certain recreational drugs. Twenty clubbers were used in all: 10 were given an ecstasy tablet to take on a Saturday night and ten were only allowed to drink alcohol. Levels of depression were measured using the Beck Depression Inventory (BDI) the day after and midweek.

When we have collected data using different subjects in each group, we need to input the data using a coding variable . So, the spread-sheet will have three columns of data. The first column is a coding variable (called something like **drug**), which, in this case, will have only two codes (for convenience 1 = Ecstasy group, and 2 = alcohol group). The second column will have values for the dependent variable (BDI) measured the day after (call this variable **Sunday BDI**) and the third will have the midweek scores on the same questionnaire (call this variable **Wednesday BDI**). The data are in Table. It can be shown that ecstasy is no more of a depressant, the day after taking it, than alcohol. Both groups report comparable levels of depression. However, for the mid-week measures the results are highly significant ($p < 0.001$). The value of the mean rankings indicates that the Ecstasy group was significantly more depressed mid-week than the alcohol group.

Pearson's Chi-square

The Pearson Chi-square is the most common test for significance of the relationship between categorical variables. For example, suppose we ask 20 males and 20 females to choose between

two brands of beverages, say Pepsi and Sprite. . If there is no relationship between preference and gender, then we would expect about an equal number of choices of Pepsi and Sprite for each sex. The Chi-square test becomes increasingly significant as the numbers deviate further from this expected pattern; that is, the more this pattern of choices for males and females differs. The value of the Chi-square and its significance level depends on the overall number of observations and the number of cells in the table.

Statistical tests

Statistical tests can be 1-tailed or 2-tailed. When either only positive or only negative differences are of interest and a directional hypothesis-or 1-tailed test-is used. Thus, in a study of growth hormone, we are interested only in the probability that the treatment group will be larger than the control group; we do not expect growth hormone to shrink patients in the treatment group. Therefore, only large differences that favor the treatment group can result in a statistically significant *P* value. When the direction of the difference is unknown, however, a 2-tailed test is preferred. Large differences between means that favor *either* the treatment group or control group can result in a significant *P* value.

A suggested check list

What variables were studied and how were they measured?

What comparisons were made?

What is the difference between the groups?

What is the 95% confidence interval for thedifferences between the groups?

What is the exact " value for the difference?

What statistical test was used in the analysis?

Did the data conform to the assumptions of the test?

Did the study have adequate statistical power?

What is the clinical importance of the difference?

Suggested reading

1. Lang T, Secic M. *How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers*. Philadelphia, PA: American College of Physicians; 1997
2. Emerson JD, Colditz GA. Use of statistical analysis. N Engl J Med 1983; 309: 709–713.

Use of Statistics in Medical Research

Gangaboraiah

Statistical methods

Statistical methods form an essential part in medical research. Its role starts from

- Selection of problem statement
- Framing appropriate research question
- Formulating an hypothesis
- Defining the aims and objectives
- Selection of suitable study design
- Designing proper methodology for collection of data
- Choosing appropriate statistical methods for analyzing data
- Arriving at valid conclusions

Study design

Designing a suitable study design is as important as choosing appropriate statistical methods for analyzing data. If the study design is poor, however strong a statistical methodology chosen is, will not helping in arriving at valid inferences of the study. Equally important is defining objectives which satisfy the following properties:

S - Smart (Specific - which describes types of statistical measures to be computed)

M - Measurable (Use suitable action verbs like: to assess, to determine, to find out, to calculate, to correlate, to associate etc., which are measurable. Avoid action verbs like: to study, to see, to observe, to know etc.)

A - Achievable (Feasibility of the study)

R - Replicable (Repeatable)

T - Time bound

Sample size

List all the required variables to measure each stated objectives. Prepare a questionnaire using the listed variables and subject it to pilot study to standardize the questions. The conduct of

pilot study also helps some times to determine the sample size, when basic details for determining the sample size are not available.

Calculation of optimal sample size for the study is important as the determination of P-value, Confidence interval, Power of study etc., are all depends on the optimal sample size. It is an optimal sample size, because small sample size may result in disproving the hypothesis what would supposed to be proved. It is unethical to choose large sample which may require huge resources to conduct the study.

Formation of hypothesis: Hypothesis is a statement which is yet to be proved. There are two two types:

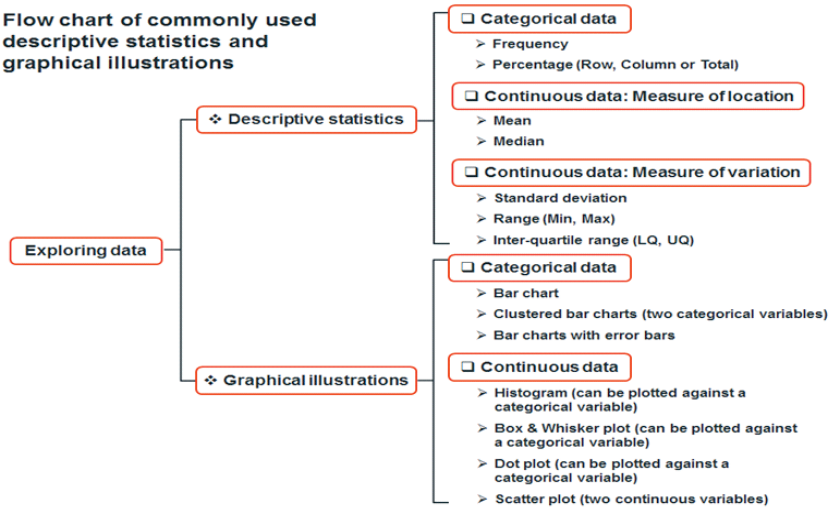
Null Hypothesis (H_0): A hypothesis of no difference. If at all any difference observed, it may be due to sampling variation.

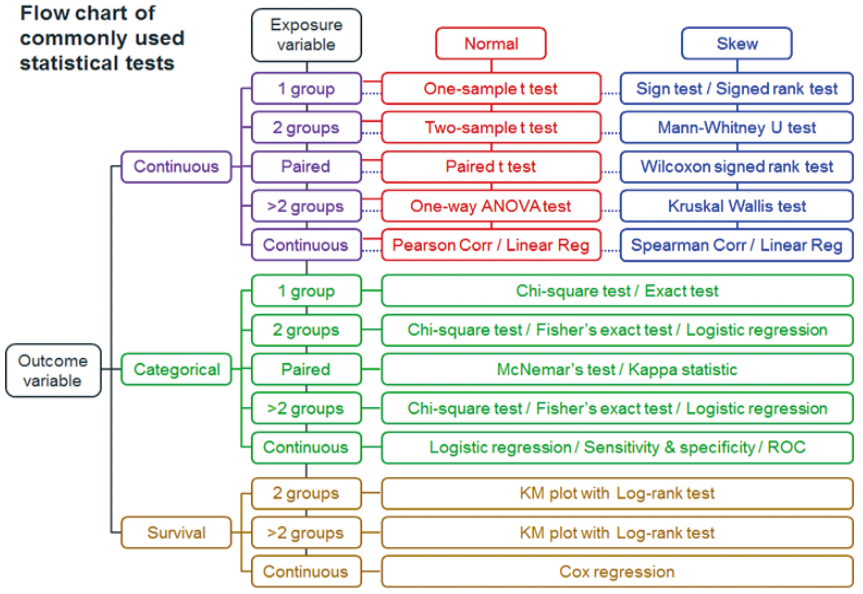
Alternative Hypothesis (H_1): It is a hypothesis what the researcher is intended to test. Usually, the objectives of the study will be converted into this hypothesis. This hypothesis is also called as Research or Study hypothesis.

Based on the direction of the research hypothesis, it will be called as one-tailed or two-tailed hypothesis. These hypotheses are to be stated at the time of preparation of the protocol of the study.

Analysis of the data

The statistical methods for analyzing the data is based on the study design, the type of variables measured and the hypothesis to be tested. The following flow chart describes the commonly used descriptive statistics, graphical representations, types of variables measured and the statistical tests to be chosen:





P - Values: P-value is the probability that any observation is due to chance alone assuming that the null hypothesis is true. Typically, an estimate that has a p value of 0.05 or less is considered to be "statistically significant" or unlikely to occur due to chance alone.

Confidence Intervals: It is the confidence with which the true value of the parameters like mean, variance, proportion etc., falls with a specified range.

Many times P-value will be a hyped value. P values provide less information than confidence intervals. A P value provides only a probability that estimate is due to chance. A P value could be statistically significant but of limited clinical significance. For example, a very large study might find that a difference of 0.1 on a VAS Scale of 0 to 10 is statistically significant but it may be of no clinical significance. A large study might find many "significant" findings during multivariable analyses.

Confidence intervals provide a range of plausible values of the population mean. For most tests, if the confidence interval includes 0, then it is not significant. Similarly, for ratios, if CI includes 1, then is not significant. If a confidence interval range is very wide, then plausible value might range from very low to very high. For example: A relative risk of 4 might have a confidence interval of 1.05 to 9, suggesting that although the estimate is for a 400% increased risk, an increased risk of 5% to 900% is plausible.

Comparison between	Mean Difference (i-j)	P-value	95% Confidence Interval		Remarks
			Lower Bound	Upper Bound	
Group 1 & Group 2	63.53	0.01	11.59	115.48	P-value shows significance but zero is outside the confidence interval
Group 1 & Group 3	35.90	0.51	-16.05	87.85	P-value do not show significance therefore, zero is included within the confidence interval
Group 1 & Group 5	52.30	0.05	0.35	104.25	P-value shows significance but zero is outside the confidence interval
Group 2 & Group 4	-42.80	0.20	-94.75	9.15	P-value do not show significance therefore, zero is included within the confidence interval

Role of Statistician

For any research under taken by the researcher, a statistical expert should be consulted right from the conception of the study till final report is prepared. The timely advice by the statistician with respect to planning, designing and analysis of data makes the research finding strong.

Statistics and Clinical Epidemiology in a nutshell

Nandkishor S. Kabra

Useful Terms

1. **Mean:** arithmetic mean- The 'mean' is the 'average' where we add up all numbers and then divide by the number of observations.
2. **Median:** Data arranged in ascending or descending order of magnitude, and then the value in middle observation.
3. **Mode:** Most commonly occurring value
4. **Mean Deviation:** Average of deviations from arithmetic man, MD= S(x-x)/n
5. **Standard Deviation:** SD is a measure of how spread out numbers/data are. Deviation just means how far from thenormal. It is "Root-Means-Square-Deviation". The formula is easy. It is the square root of the Variance.
6. **Standard Error/Standard Error of Mean:** It is the standard deviation of the means. It is measure of the simple error and is given by the formula SD/On
7. **Skew:** symmetry of distribution
8. **Kurtosis:** Flatness or peakedness of distribution
9. **Range:** lowest-to-highest
10. **Interquartile range (IQR):** IQR is a measure of variability based on dividing a data set into quartiles from Q1 to Q3.

    Quartiles divide a rank-ordered data set into four equal parts. The values that divide each part are called the first, second, and third quartiles, and they are denoted by Q1(25^{th} percentile), Q2 (50^{th} percentile), and Q3(75 percentile), respectively
11. **P value**: The probability that a particular result would have happened by chance. Probability of obtaining as or more extreme results provided that the null hypothesis is true.

* The $p < 0.05$ is wholly arbitrary

* Statistical significance does not translate in to clinical importance.

12. **Confidence interval (CI):** A CI gives an estimated range of value which is likely to include an unknown population parameter, the estimated range being calculated from a given set of sample data.
    a. A confidence interval is an interval estimate of a parameter of Interest
    b. Instead of estimating the parameter by a single value, an interval of likely estimates is given
    c. CI are used to indicate the reliability of an estimate
13. **Defomotopm pf 95% CI:** The interval computed from the sample Data which, were the study repeated multiple times, would contain the true effect 95% of the time.
14. **Type I Error:** False positive-rejecting the null hypothesis when it is true, false alarm
15. **Type II Error:** False negative-accepting the null hypothesis when it is false, failed alarm
16. **Type III Error:** Correctly reflecting the null hypothesis for the wrong Reason (right answer for wrong hypothesis)
17. **Type IV Error**: Incorrect interpretation of a correctly rejected hypothesis (wrong answer obtained with the wrong test, overestimation of risks that leads to rejection of an efficacious therapy.
18. **Type VError**: made-up, fabricated, fraudulent results
19. **Type O Error:** From the point of view of confidence intervals,getting it wrong is simply a matter of the population value being outside the confidence interval.
20. **Probability (P)**

Probability

Frequency definition:

$$P(\text{event}) = \frac{\text{Number of times event occurs}}{\text{Number of times event could have occurred}}$$

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21. **Odd (O)**: Odds are alternative way of describing the chance of an event Odds = Event/ No of event = P/(1-P) For calculating probability from odds, P= O/(1+O)

22. **Risk Difference (RD):** This measure of effect tells us what proportion of patients are spared the adverse outcome if they receive the experimental therapy.

23. **Relative Risk (RR):** This measure tells us the proportion of the original risk of outcome that is still present when patients receive experimental therapy.

24. **Relative Risk Reduction (RRR):** An estimate of the proportion of baseline that is removed by the therapy. RRR= 1-RR

25. **Correlation**: Correlation examines the strength of the relation Between two variables, neither of which is necessarily Considered the target variable.

26. **Regression:** Regression examines the strength of the relation Between one or more predictor variables and a target variable.

27. **Univariate analysis**: Univariate analysis deals with one predictor Variable

28. **Multivariate analysis**: It deals with multiple predictor variables.

29. **Superiority trials:** Trials designed to demonstrate that one treatment is more effective than another. Purpose is to detect differences between two drugs.

30. **Non-inferiority trials:** Trials designed to demonstrate that a treatment is at least not appreciably worse than another. Their purpose is to demonstrate that a new drug is not worse than an active comparator by more than pre-specified amount. These trials are designed to ensure that new therapeutic is not unacceptably worse than the standard therapy.

31. **Equivalence trials**: Equivalence trials are designed to demonstrate that one treatment is as effective as another. Purpose is to confirm absence of meaningful difference between treatments. equivalence is inferred when entire

confidence interval falls exclusively within equivalence margins (between "– and +")

32. **Power of a study:** It is the ability to study to find difference if it Exists.

33. **Blinding:** Blinding in a study can be attempted at following levels in a RCT participants, Health Care Providers, Data collectors, Judicial assessors of outcome, Data analysts, data safety and Monitoring Committee, Manuscript writers.

34. **Bias**: Systematic deviation from the truth

    a. ***Selection bias*** (incomplete randomization)-How patients enter in the study?

    b. ***Performance bias*** (care provided to groups)-additional or co-interventions

    c. ***Exclusion bias*** (Withdrawal from trial)

    d. ***Detection bias*** (Outcome assessment)-How outcomes are measured?

35. **Stratification**: Stratification is the process of grouping members of the population into relatively homogeneous subgroups before sampling

36. **Block Randomization**: Random allocation can be made in Blocks in order to keep the sizes of treatment groups Similar at every step in the study.

37. **Intention to treat on intent to treat (ITT) analysis**: It is an analysis based on the initial treatment intent, not on the treatment eventually administered. Use every subject who was randomized according to randomized treatment assignment. Ignore noncompliance protocol deviations, withdrawal and anything that happens after randomization. ***As randomized, so analyzed.***

38. **Per-Protocol (PP) analysis/ On treatment analysis**: PP analysis is in contrast to the intention to treat analysis, is a strategy of analysis in which only patients who complete the entire clinical trial or other procedure analyzed, not like the ITT analysis which also included the patients who dropped out.

39. **Treatment received analysis:** This is another approach to analyze all participants according to the treatment they actually received, regardless of which treatment they were originally allocated.

40. **Validity:** The degree to which the results of a study are Likely to be true, believable and free of bias.

    a. The **internal validity** of a study refers to the integrity of the experimental design.

    b. The **external validity** of a study refers to the appropriateness which its results can be applied to non-study patients or population.

41. **Sensitivity**

    a. The proportion of people with the target disorder who have a positive test result

    b. A proportion of truly diseased persons, as measured by the 'gold standard', who are identified as diseased by the test under study.

    c. Positive in disease (PiD) rate

    d. True Positive Rate

42. **SnNout:** When a test has a high sensitivity, a negative test result can help to rule out the diagnosis.

43. **Specificity**

    a. The proportion of patients without the targetdisorder (healthy people) who have a negative test result.

    b. Negative in health (NiH) rate

    c. True Negative Rate

44. **SpPin**: When a test has a high specificity, a positive test rules in the diagnosis

45. **Positive Predictive Value**

    a. How often the disorder is present if test is positive?

    b. Predictive value of a positive test

    c. Post-test probability of a positive test

d. Proportion of people with a positive test who have the target disorders

46. **Negative predictive value**

a. How often the disorder is absent if test is negative?

b. Predictive value of a negative test

c. Proportion of people with a negative test who are free from target disorder.

47. **Likelihood Ratio (LR):** The ratio of the probability of A test result among patients with the target disorder (diseased) to the probability of that same result among patients who are free of the target disorder (non-diseased). "***Likelihood ratios are odds, odds are not the same as probability***".

The LRs indicate by how much a given diagnostic test result will raise or lower the pre-test probability of the target disorders.

a. LR = 1, no difference

b. LR > 1 indicates that finding/test makes the disease more likely

c. LR < 1 indicates that finding/test makes disease Less likely

48. **LR of a Positive Test**

a. Ratio of the probability of a true positive result if the disease is present to a false positive result if the disease is absent

b. How much more likely is positive test to be found in a person with as opposed to without, the condition/disease?

49. **LR of a Negative Test**

a. Ratio of the probability of a falsie negative result if the disease is present to the probability of a true negative result if the disease is absent

b. How much more likely is negative test to be found in a person with, as opposed to without, the condition/disease?

50. **Receiver/Relative operating characteristic (ROC) or simply ROC curve**: It is a graphical plot of the true positives (sensitivity) on Y-axis *versus* false positivity(1-specificity) on X-axis
51. **Overview:** A term for any summary of the medical Literature
52. **Meta-analysis:** Systemic review that uses Quantitative methods(statistical synthesis) to summarize the results. A review in which bias has been reduced by the systematic identification, appraisal, synthesis, and, if relevant, statistical aggregation of all relevant studies on a specific topic according to a predetermined and explicit method.

Table1: Graphical versus Numerical methods of assessing normality of data

	Graphical methods	Numerical methods
Descriptive	Stem-and leaf-leaf plot Skeletal/ Box plot Dot Plot Histogram	Skewness Kurtosis
Theory-driven	P-P plot Q-Q plot	Shapiro-Wilk, Shapiro, Francis Test, Kolmogorov-Sminrov test (Littlefors Test), Anderson-Darling/Cramer-von Mises test, Jarque-Bera test, Skewness-Kurtosis test

Table 2: Relationship between common language and hypothesis testing

Common language	Statistical statement	Conventional test threshold
"Statistically significant" "Unlikely due to chance"	The null hypothesis wasRejected	P<0.05
"Not significant" "due to chance"	The nullhypothesis could Not be rejected	P>0.05

Table 3. Examples demonstrating relationship between 95% CIs and P values

Example	Effect Measure	Value for no Difference	CI includes No difference	Statistically Significant (P<0.05)
The average weight Loss was 7 labs (95% CI, -3 to 17)	Difference in means	0	Yes	No
42% absolute reduction In the need for intubation (95% CI, 7% to 70%)	Difference In proportion	0	Yes	No
The relative risk for cancer was 2.3 for smokers compared with non-smokers (95% CI, 1.8 to 3.0)	Relative risk	1	Yes	No
The odds ratio for readmission was 0.8 for managed care patients (95% CI, 0.3 to 1.2)	Odds ratio	1	Yes	No

Table 5: Interpretation of p value

P>0.1	Little evidence to suggest a real difference
0.05 <P<0.1 A	"trend" towards or a "suggestion" of a real difference
0.01 <P<0.05	Evidence to indicate a real difference Data are Statistically significant
0.001<P<0.01	Strong evidence to indicate a real difference Data are Highly significant
P<0.001	Strong evidence to indicate a real difference Data are Highly significan

Table 6: Ideal Study Design according to purpose of study

Purpose	Study Observational	Design Intervention
To estimate prevalence	Cross sectional	
To determine natural history	Cohort	
To identify causes or risk factors or people at high risk	Cohort, case-control or cross sectional	Randomized trial
To prevent disease		Randomized trial
To alter course of disease		Randomized trial

Table 7: Details of Reporting Guidelines for Different study designs

Study design	Guideline/Statement	Source
Randomized Controlled trial	Consolidated standards of Reporting Trials (CONSORT) Statement	http://www.consort-statement.org
Diagnostic accuracy studies	Standards for Reporting of Diagnostic Accuracy (STARD)	http://www.stard-statement.org/
Observational studies	Strengthening the Reporting of Observational Studies. In Epidemiology (STROBE)	http://www.strobe0statement org/ index.php?id=available-checklists
Systematic reviews/Meta-analysis of RCT	Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)	http://www.prisma-statement.org
Meta-analyses of observational studies	Meta-analysis of Observational Studies in Epidemiology (MOOSE)	www.consort-statement.org//o=1347
Case reports	CaRe guidelines	http://www.care-statement.org/

Table 8. Type of Data and choosing the correct Statistical Test

Type of data	Two treatment groups consisting of different individuals	3 or more Treatment Groups consisting of different individuals	Before and after a single treatment in the same individual	Multiple Treatment In the Same individual	Association between two variables
Nominal (proportion)	Chi Square Fisher Exact	Chi Square	McNemar's Binomial	Cochrane Q	RR, OR, RD, ARD,NNT, NNH, Logistic regression
Ordinal, ranked, Numerical discrete and continuous (if not normal distributed)	Mann-Whitney rank sum test	ANOVA by Krysjak0allis MANOVA	Wilcoxon Signed rank test Sign test	Friedman Statistics	Spearman rank Correlation Kendall Tau Coefficient Gamma
Numerical, Discrete and continuous (if normally distributed)	Unpaired (Two sample) t-test	ANOVA (t-test) MANDOVA	Paired (one sample) t-test	Repeated measures ANOVA	Linear regression (least square method), Pearson Product moment correlation
Survival time	Mantel Haenszel chi square	Log rank chi square	Conditional proportional hazards	Conditional proportional hazards	

Table 9: RCT calculations

Outcome	Disease +(event)	Disease –(no event)	Total
Treatment Group	a	b	a+b
Control Group	c	d	c+d
Total	a + c	b + d	N= a+b+c+d

Absolute risk in Treatment Group = EER= a/(a+b)
Absolute risk in Control Group =CER=c/(c+d)
Risk Difference (ARR/ARD/RD/ERD)=RD=CER-EER={c/(c+d)}-{a/(a+b)}
Number Needed to Treat =NNT=1/RD..when negative called as NNH
Relative Risk (risk ratio)=RR=EER/CER={a/(a+b)}/{c/(c+d)}
Relative Risk Reducation=RRR=RD/CER=(CER-EER)/(CER)=1-RR
OR (Odds Ratio, ratio of odds, cross product ratio)=ad/bc

Table 10. RCT Calculations: Solved Example: TIPP Study

Outcome	PDA	No PDA	Total
Prophylactic Indomethacin	a 142	b 459	a + b 601
Placebo Group	c 301	d 300	c + d 601
Total	a + c 443	b + d 759	N=a+b+c+d 1202

RD= CER-EER= {c/(c+d)}- {a/(a+b)}= 0.50 – 0.24 =0.26
NNT= 1/RD= 3.84=4
RR= EER/CER = {a/(a+b) }/{c/(c=d)}=0.24/ 0.50 = 0.48
RRR= (CER-EER) /(CER) = 1 -RR = 1-0.48=0.52
OR= ad/bc = (142 x 300)/ (459 x 301) = 42,600/1,38,159= 0.308

Table 11: Interpretation of Diagnostic Test

Outcome	Target disease +ve	Target disease +ve	total
Diagnostic test +ve	TP a	FP b	a + b
Diagnostic test -ve	FN c	TN d	c + d
Total	a + c	b + d	N = a+b+c+d

Target disease present= a+c
Test positive+ a=b
Accuracy = (a+d)/(a+b+c+d)
Sensitivity (TP Rate)= a/(a+c)
Target disease absent = b+d
Test negative= c+d
Prevalence= (a+c)/(a+b+c+d)
Specificity (TN Rate)= d/(b+d)

Positive Predictive Value = a/(a+b)
Negative Predictive Value = d/ (c+d)
Likelihood Ratio of a positive test = {a/(a+c))]/{b/(b+d)}
Likelihood Ratio of a negative test = {c/(a+c)}/(d/(b+d)}

Sample size calculation

When?

- Quantitative studies
- Not required for qualitative research(note: this means formal qualitative methods, such as content analysis)
- May not be required for certain preliminary pilot studies
- However, such studies will often be performed prior to performing definitive study or applying for funding

Why?

- In studies concerned with estimating some characteristics of a population (e.g. the prevalence of asthmatic children), sample size calculations are important to ensure that estimates are obtained with required precision or confidence
- In studies concerned with detecting an effect (e.g. a difference between two treatments, or relative risk of a diagnosis if a certain risk factor is present versus absent), sample size calculations are important to ensure that if an effect deemed to be clinically or biologically important exists, then there is a high chance of it being detected. i.e that the analysis will be statistically significant.
- If the sample is too small, then even if large differences are observed, it will be impossible to show that these are due to anything more than sampling variation.

What all is required?

1. Type of outcome Nominal, Ordinal, Rank, Numerical, Discrete, and, Numerical-Continuous
2. Design(2-arm, k-arm, cross-over, factorial, repeated measures, etc)
3. Statistic (e.g. x sample mean estimates, m population mean), one sided or two-sided test
4. Type of effect measure (MD, RD, RR, PR, HR)
5. Estimate of variability of control group ($^2_{c)SD\ of}$continuous outcome variables
6. Significance level: type 1 Error (alpha), False positive
7. Desired power (1-b) or Type II Error (b)
8. Minimally clinically important effect (d_o)
9. Rough idea of cost per patient
10. Software, Statistician
11. Choose correct formula

Development of Questionnaire in Research

Amol Dongre

Introduction

Questionnaire is a commonly used quantitative data collection instrument in the field of public health, educational research and evaluation.[1] When the instrument is self-administered, it is called as 'questionnaire' and when it is filled by the investigator or enumerator; it is known as 'schedule'.

The choice between questionnaire and schedule depends upon the purpose of the research, mode of administration, characteristics and type of respondents and other logistics arrangements. Though development of questionnaire is an important scientific step in research process, it receives less attention as compared to other steps such as formulating the research question, deciding the sample size and sampling, development of study design, data collection and analysis plan. Hence, as consequence, the poorly developed questionnaire can lead to poor or inadequate measurement of the central phenomenon of the interest. Often, there is a mismatch between the objectives and actual content of the questionnaire. It is commonly experienced challenge for novice researcher to develop a valid and effective tool for measurement.

Instrument: There are three ways for obtaining the instrument:

1) Develop your own instrument,
2) Borrow and make it specific to your context, and
3) Locate one and use it as it is.

Out of these three, borrowing the instrument and modifying it to your context seems easiest approach. It requires permission to make changes according to your requirements. Noteworthy, most of these instruments might not cover the variables under proposed investigation; hence, one has to develop a questionnaire specific to

the purpose of the study. Thus, it is vital to know the steps in questionnaire development leading to reliable and valid tool for the measurement with less measurement error.

Steps in questionnaire development[2]

Developing an instrument consists of several steps such as deciding the purpose of the research, literature review, refining the research question, identifying the variables to be measured, creating the questions\statements and finally pilot testing and revising it. It also requires careful consideration of practical issues such as time, cost, staffing and ethical issues.

Step-1: First step is to work out a research question and decide the information that would be required. If research topic is new or the context is different, then, pre-survey qualitative research is preferred to begin with it. It helps the researcher to understand the phenomenon from the participants' view point. The themes generated from qualitative enquiry helps in item generation or hypothesis formation. Most of the exploratory kind of mixed methods research beings with the qualitative exploration leading to a context-specific instrument development for quantitative phase.

Step-2: Next step would be to search the scientific literature in the online data base using some carefully selected 'keywords' and 'appropriate search strategy'. It is better to prefer recently published full text articles for the literature review. It helps in identifying what is already known and the gaps in the existing literature. The findings from pre-survey qualitative research and the literature help in developing a 'conceptual framework' which is a theoretical framework of assumptions and ideas explaining a concept or central phenomenon under the investigation.

Step-3: This is useful to further refine the research question addressing the gap in the existing literature.

Step-4: It is helpful to decide the broad domains and work out the number indicators to be measured under each domain. Once, the indicators are identified, meaningful close-ended questions with suitable responses are framed to measure each of these indicators (Table 1). These questions ultimately measure the various domains. One should also keep in mind the analysis plan, as the number and type of variables selection and their units of measurement have implications on analysis and results. If the purpose is to develop scale

type instrument, then this step helps in item generation. Scales are devices used to quantify a subject's response on a particular set of variables. These types of scales are common in educational research for measurement of complex concepts such as attitude.

Table 1: Example of domain to indicator to questions on Maternal Health

Domain	Indicators	Questions
Maternal factor	No of ANC visits No of IFA tablets consumed No of TT Injections	How many ANC visits have you done? How many IFA tablets did you consume during this pregnancy? How many TT injections have you taken?
Anthropometry	Height	Measure weight (kg).....
	Weight	Measure height (cm).....

Step-5: Once the questionnaire is developed, it has to be pilot tested. In a conventional pilot testing, a sample of 20-30 participants in the area other than the study site are selected and interviewed using the draft version of the questionnaire. The purpose is to check, if the questions and its close ended responses are appropriate. It is also a time to check the order of the questions in the questionnaire, wording and phraseology of questions. It is good to use simple language, avoid short form and be specific. The revised version of the questionnaire can be shared with some experts in the given field for their feedback and face validation.

In scale development, this is seen as 'first' pilot test, where the subjects are briefed about the purpose and then the tool is administered to them. Item analysis is done on the data collected to calculate the reliability. The reliability coefficient (alpha) can range from 0 to 1, with 0 representing an instrument with full of error and 1 representing total absence of error. A reliability coefficient (alpha) of .70 or higher is considered acceptable reliability. Later, 'second' pilot test is done to check the validity of the instrument.[1]

Step-6: It is time to check the number of questions in the questionnaire, formatting, layout and length of questionnaire. The number of questions should be adequate enough to achieve the objectives of the research. If the questionnaire is self-administered,

then consider the primacy effect due to visual presentation, where the respondents tend to tick mark the initial responses of the close-ended questions. Similarly, the investigator-administered questionnaire has a risk of 'recency effect' due to auditory presentation, where the participants prefer to select the last options of the close-ended questions. To avoid this, it is recommended to keep few and specific responses to close-ended questions. The wording of the question should simple, contextualized and it should measure one concept at a time.

Step-7: The investigator should think of practical issues such as amount of time required to administer the questionnaire, ethical issues, cost and staff required for carrying out the study. The questionnaire should begin with the general questions with more sensitive questions towards the end. The investigator should be sensitized to the nice way of putting sensitive questions to the participants. One should also have a plan to safely store this collected information to ensure the privacy and confidentiality of the participants.

Points to consider while selecting instrument for context specific modifications[3]

1. Check if the authors have developed this instrument in recent time. With the rapid expansion of knowledge in research, instrument over 5 years old might be outdated.
2. Is the instrument widely cited by other authors? Frequent use by others indicates its wider acceptability and endorsement by peers.
3. Is there information available for the reliability and validity of the scores from past uses of the instrument
4. Does the procedure for data collection fit the research question/hypothesis in your study?
5. Does the instrument contain accepted scales of measurement?
6. Please check, if there are any permissions required to use the instrument.

Summary

Ask those questions which are specific, focused and relevant to research question and view questions from respondent's angle. Overall, it is important to consider all the above mentioned steps and issues in effective instrument development or selection.

References

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3. Creswell JW. Educational Research: Planning, conducting and evaluating qualitative and quantitative research. Pearson Education, New Jersey, USA.

Clinical review article

PS Shankar

Introduction

A review article is a critical evaluation of material that has already been published. The author of a review article evaluates all previously published literature on that topic and organizes it in a proper way. The write up has to clarify the current research on that topic.

It should be noted that review article is not a research article. Review article evaluates the evidences presented in a research article.

Types of review articles

There are different types of review articles:

1. Clinical review (Update)
2. Systematic review
3. Meta-analysis

Clinical review: Clinical review is an update that discusses a topic broadly and makes selective review of the medical literature that has been published on that topic e.g. the diagnosis and management of Bronchial asthma.

Systematic review: The review makes an attempt to examine the medical literature and summarizes all relevant information, and formulates the best approach that can be adapted to diagnose and treat a particular condition.

Meta-analysis: Meta-analysis is a quantitative systematic review. It concentrates on a focused clinical question and tries to get answer by making a statistical analysis of pooled research studies. E.g. do inhaled corticosteroids reduce mortality in chronic obstructive pulmonary disease?

Selection of topic

When intend to write a review article we have to select a common clinical problem. One should not select a rare condition or an unusual manifestation of a disorder. The review becomes useful if the problem selected provides new information about the diagnosis and treatment of a particular disorder.

Types of evidence

While providing evidence in the article, generally 'Shaughnessy and Slaw son's concept is followed. The evidence may be either patient-oriented or disease oriented. In the former it deals with outcomes of importance that includes the changes in morbidity and mortality, and quality of life. In the latter, the evidence deals with surrogate end points such as changes in laboratory values or other measures of response.

Format of review

The format of review consists of the following:

Abstract- Introduction-Methods-Discussion-References

Abstract

The abstract must be brief consisting of 200 words or less. It provides a brief synthesis of the whole review. Any person who reads it can determine its usefulness immediately. Generally, the writing of the abstract is considered very difficult. Though the article begins with an abstract, it should be written after completion of writing of the whole review. Thus, the abstract appears first in the article but is written last. One should make the abstract interesting so that it should be a stimulus to read the entire article. While writing the abstract, one should take precaution that abstract and the subsequent introduction contains the same information.

Introduction

The introduction of the article must brief and at the same time it should provide highlights of the article. The purpose of writing the article should be unraveled in the introduction. The introduction should define the topic and the purpose of the review. It should briefly discuss the epidemiology of the condition.

Methods

As review article is not an original research, the write up should briefly give information how the literature search was conducted. The major sources of evidence should be mentioned. All relevant research evidence should be included. There should be a critical evaluation of the quality of research reviewed.

The reviewer should not be biased. He should not resort to make selective references of only information that supports the conclusions made. Often there are controversies on a topic and the reviewer must discuss the available information on the subject.

Discussion

Generally the discussion is followed on a time-honored format. Since it is a clinical topic the pattern will be etiology,

pathophysiology, pathogenesis, clinical presentation, diagnostic evaluation, differential diagnosis, prognosis, treatment and prevention. It should conclude with a note on future direction. Tables, figures and illustrations are to be used to highlight the key points. A step-wise algorithmic approach to the diagnosis and treatment will be useful.

The information provided in the review is generally not found in the text books. The reviewer should not leave any land mark article and different meta-analyses. The article should be in a position to give evidence-based recommendations.

Key points

At the end of the review article, key points that include diagnosis and treatment of a specific condition should be highlighted.

References

The references should include the current and most important publications that support the important statements. There should be references for the studies referred and the new information provided. Controversial information should have proper references. References are to be provided to the specific quantitative data.

How to write a case report?

PS Shankar

Introduction

Clinical practice gives something new to the searching eyes. This information is communicated to others in the form of a patient case report. The report is made when the clinical presentation is unusual or previously unknown. One can prepare a report of an unusual presentation or complication of a known disease. Sometimes the report may contain information about a new approach to the management of the common clinical disorder. Case report is considered one of the simplest methods of communication and it gives an opportunity to develop writing skills.

Case Report

When one has recognized an unusual case in the ward, a detailed note about the condition has to be prepared with the evolution of the symptoms, unusual physical findings, diagnostic abnormalities, the course of the disease and its response to the treatment. Then one should search literature thoroughly. The PubMed, Medline, Ovid, Embase and Google scholar help in finding out more information about the case. One should search the National journals so as to get information about similar cases in the country. Even case reports that have appeared in the journals that are not indexed also provide useful information.

Generally, case report will be of 1500-2500 words.

Format

The format of a patient case report consists of the following six sections**:**

- abstract
- introduction
- description of a patient case report
- discussion
- summary
- references

Title

The title of case report should be able to provide the description of the case in an accurate manner succinctly. Thus, the title should be 'concise, functional and informative'.

Author (s)

Following the title there should be a list of authors(s). Generally, they are written with the last name followed by initials of each author. Then there should be the name of the Department and the institution from which the case is reported. The name of the place, state and country are to be mentioned. There should be the name and address including e-mail ID of the author to whom the queries, proofs and requests for reprints should be sent.

Abstract

The case report begins with the abstract. It should be written clearly and briefly. It should include main text of the case report. Generally, it should be written in 100-250 words. It should be followed by mentioning a list of key words. The maximum number of key words is five and they should be relevant to the contents of the article. It should help the indexers and archivists to locate the article.

Introduction

The main case report is begun with an introduction. It should provide the essentials of the subject, purpose and importance of the case report. There should be mention about the rarity of the condition. It should briefly narrate about its unusual features. The introduction should be brief and should be able to provide the gist of the presented case.

Case Presentation

The main part of the case report is its presentation. It should consist of a description of the developments of the events in a chronological order. The report should consist of the history, physical examination; report on laboratory work up and imaging studies, treatment including surgical procedures and outcome. It should give information on the biopsy and histopathological report. All this information should be mentioned in an order without any heading.

Before presenting the history, the demographic information of the patient (age, sex, height, and weight) are to be mentioned. While writing the report one should avoid unnecessary details. Only important positive and negative findings that are relevant to the case are to be mentioned. The report should be illustrated with figures,

graphs, photographs, radiograms and other images. The illustrations help in understanding the case description.

While preparing the report one has to use the standard abbreviations. The abbreviations should be avoided in the title and abstract. It is necessary to give full term for which abbreviation stands and it should be mentioned when first used. The standard unit of measurements can be used without any difficulty.

The name or initials of the patient and hospital numbers should not be used as they help in recognition of the patient. Even in the photographs the patient must not be recognizable. If one uses the photographs where the facial features can't he hidden, prior written consent from the patient has to be obtained.

Discussion

Discussion forms the most important part of the case presentation. The unique features exhibited by the patient should be discussed and compared with those published in the literature. Its unique features should be highlighted. Normally the discussion expands the introduction and explains the importance of the case. The literature available on the topic should be discussed with reference to the findings in the case. In light of the available information, the clinical findings should be discussed and it should give a clear message to the reader.

Summary

At the conclusion, there should be a brief summary and it should summarize the essential features mentioned in the case report

References

There should be 5-10 references that are appropriate to the case.

The correspondence

PS Shankar

Introduction

The correspondence in the Medical Journal consists of Letter to the Editor. This has been considered an important academic activity. In the letter the reader makes comments on previously published articles in the journal. Also, one may write on any subject of interest to the reader of the journal. But publication of such letter in the journal is the prerogative of the editor.

Letter to the Editor

The letter should be addressed 'to the Editor'. The letter is a short communication. It provides an opportunity to communicate between the author of an article published in previous issue(s) of the journal and the reader of the journal. Thus, it facilitates continued dialog about the article.

The letter is not categorized as an original research. However, it provides new useful information. It helps to make corrections of the statements made in the article. It provides alternate view points on the subject and adds experience of others to the original research. One can seek clarification about the information mentioned in the article published. The readers view point provides additional information.

Presentation

The letter should be clearly written. It should address to specific points mentioned in the article and the sentences should be properly constructed. The letter must be brief and concise. Generally, it is restricted to 175 words. Sometime the number of words may be more especially when the letter is not related to the journal article. It must be noted that references are not included while calculating the number of words. The letter must be submitted within 3 weeks following publication of article. One can include a figure or a table to highlight the points. While preparing the letter the author should keep in mind that the write up to be objective, constructive and purposeful. There should not be any repetition or unnecessary details.

Author(s)

Generally the number of authors is restricted to 3. Their names

should appear at the end of the letter. It should contain their full mailing address and e-mail address.

References

References are cited after mentioning the names of authors. The number of references cited should not be more than 5. Generally, the references are cited without any heading.

References

PS Shankar

Introduction

References are cited in Vancouver style. This is a citation style used by most biomedical journals. It is based on a standard adapted by the National Library of Medicine (NLM) for databases such as Medline. It was developed in Vancouver, Canada in 1978 by Editors of Medical Journals who now meet annually as the International Committee of Medical Journal Editors (ICMJE).

More than 500 Medical Journals use this style of references. This numerical system has been preferred referencing style for health sciences.

In the text citation

The references are numbered consecutively in the order they are first mentioned (cited) as the source of information. Each reference number is placed in parenthesesthroughout the text, tables and legends. The number assumes importance as identification of that source. If the same reference is used again, the original number is used again. Instead a superscript number may be inserted in the text.

A consecutive number is allocated to each source as it is referred to for the first time. The number is placed outside periods and commas; inside colons and semicolons. Where more than 2 references are cited at a given place in the manuscript, hyphens are used to join the first and last numbers of a closed series. It is advised to use commas without space to separate two citations.

- Care has to be taken to use direct quotations sparingly. If a direct quotation is necessary, quotation marks have to be placed around quotation and the reference has to be numbered.
- The tables are to be numbered consecutively. A brief title has to be provided for each table and it should be mentioned in the text.
- Avoid personal communicationas a reference unless it

provides essential information that is not available from a public source. It should not be numbered as a reference. Instead the name of person and date of communication should be mentioned in parenthesis in the text.

In the reference page

The references are mentioned at the end of the text. The references are listed numerically. It is necessary to list all references in order by number and not alphabetically. Each reference is listed once only since the same number is used without any alteration throughout.

- While mentioning the authors, use their last name and mention initials. If the number of authors exceeds six, mention the first six followed by 'et al'.
- The Books with chapters when cited, write the individual authors of the chapter, and then mention the title of the chapter, followed by 'In', the editors name and the book title. While mentioning the book title, and chapter title capitalize the first letter of the first word in the title and the rest of the title should be in lower case with the exception of proper names.
- Caution has to be taken not to underline the title. Italics should not be used.
- The journal titles are to be abbreviated as in Pub Med's Journal data base. There is period after title. Year semicolon, volume, issue number should be in parenthesis then colon. Page range and a period. E.g. Brain Res. 2002; 935(2):1-4. The issue number may be omitted if the journal is paginated continuouslythough out the year. For chapters in book the page range may be given. For books, page number is not necessary.
- For a standard journal article the reference is made as follows. Pasternak B, Hived A. Use of Protein-Pump inhibitors in early pregnancy and the risk of birth defects. N Engl J Med 2010: 363; 2113-23
- When there are more than 6 authors, the citation is made as follows: Gooley TA, Chien JW, Pergam SA, Hingorani S, Sorror MI, Boeckh M, et al. Reduced mortality after allogeneic hematopoietic-cell transplantation. N Engl J Med 2010: 363; 2091-101
- Some journals give a lengthy reference sometimes even up to 117 names (!) which must be avoided.

- Personal author in a book is mentioned as follows: Behera D. Text Book of Pulmonary Medicine, Second Edn (in two volumes), New Delhi, Jaypee Brothers, 2010
- When Editor is an author, it is mentioned as follows: Shankar PS (Ed) Respiratory Futurology, Mumbai, Academy of Respiratory Medicine, 2010
- Chapter in a book is cited as follows: Seeli JR, Sandford K. Molecular mechanisms of disease in Boon NA, Colledge NR, Walker BR, Hunter JAA (eds) Davidson's Principles and Practice of Medicine, 20thedn, Edinburgh, Churchill Livingstone, 2006

It is best to follow the guidelines given to the authors by the journal or refer to the guidelines of international committee of medical journal editors by visiting the web link - http://www.icmje.org/recommendations/browse/manuscript-preparation/preparing-for-submission.html

Scientific Writing: Medical Literature, Online Publications, Indexing, Citation Index, Impact Factor, Research Gate Score – An Overview

Rama Rai Urs

Introduction

Knowledge is power

Knowledge is defined as "justified true belief." It includes facts, information, descriptions or skills acquired through experience or education. It can refer to the theoretical or practical understanding of a subject. Knowledge can be implicit (as with practical skill or expertise) or explicit (as with the theoretical understanding of a subject); it can be more or less formal or systematic. The ultimate purpose of science is to contribute to the well-being of humanity. The sources for finding journal impact factors and other tools which will help to measure a journal's credibility and influence.

Scientific writing

When you write about scientific topics to specialists in that field of science, we call that scientific writing. When you write to non-specialists about scientific topics, we call that science writing.

The scientific paper has developed over the past three centuries into a tool to communicate the results of scientific inquiry. The main audience for scientific papers is extremely specialized. The purpose of these papers is twofold: to present information so that it is easy to retrieve, and to present enough information that the reader can duplicate the scientific study. A standard format with six main parts helps readers to find expected information and analysis.

- Title--subject and what aspect of the subject was studied.
- Abstract--summary of paper: The main reason for the study, the primary results, the main conclusions

- Introduction--*why* the study was undertaken
- Methods and Materials--*how* the study was undertaken
- Results--*what* was found
- Discussion--*why* these results could be significant (what the reasons might be for the patterns found or not found)

Medical Knowledge

The word medicine is derived from the Latin 'Arsmedicine' meaning the art of healing.

Medicine is the field of applied science related to the art of healing by diagnosis, treatment, and prevention of disease. It encompasses a variety of health care practices evolved to maintain and restore health by the prevention and treatment of illness in human beings.

Contemporary medicine applies health science, biomedical research, and medical technology to diagnose and treat injury and disease. Typically, through medication or surgery, but also through therapies as diverse as psychotherapy, external splints and traction, prostheses, biologics, ionizing radiation and others.

Medical Literature

Medical literature refers to articles in journals and texts in books devoted to the field of medicine. Contemporary and historic views regarding diagnosis, prognosis and treatment of medical conditions have been documented for thousands of years.

The Edwin Smith papyrus is the first known medical treatise. Initially most described inflictions related to warfare. This was because war was the most important part of society and it was the most common way of contracting health problems. Exponential increase of knowledge is estimated that the doubling time of medical knowledge in 1950 was 50 years; in 1980- 7 years; and in 2010 – 3.5 years. In 2020 it is projected to be 0.2 years – just 73 days

Sources of information

There are 3 important sources of information. They are;

- Human Sources
  – Parents, Teachers, Guides, Researchers, Clinicians, Doctors and Experts
- Institutional Sources
  – Schools, Colleges, Universities, Apex Bodies, Hospitals, Institutions and Organizations of Research and Development
- Documentary Sources
  – Primary Sources, Secondary Sources and Tertiary Sources

Documentary Sources

- Primary Sources
  – Scholarly Journals, Text Books, Reference Books, Monographs, Treaties, Manuscripts, Clinical Reports, Standards, Patents, Specifications, Grey Literature etc.
- Secondary Sources
  – Dictionaries, Encyclopedias, Directories, Indexing& Abstracting Tools, Bibliographies etc.
- Tertiary Sources
  – Catalogue of Catalogues, Bibliography of Bibliographies, Directory of Directories etc.

Online publications

An online publication devoted to metadata, its types and uses, and how it can improve access to digital resources. Electronic publishing also referred to as e-publishing or digital publishing.

It includes the digital publication of e-books, EPUBs, Digital Magazines (also sometimes known as electronic articles), and the development of digital libraries and catalogues.

Electronic publishing has become common in scientific publishing where it has been argued that peer-reviewed. Scientific journals are in the process of being replaced by electronic publishing.

It is also becoming common to distribute books, magazines, and newspapers to consumers through tablet reading devices, a market that is growing by millions each year, generated by online vendors such as Apple's iTunes bookstore, Amazon's bookstore for Kindle, and books in the Google Play Bookstore.

Electronic publishing is increasingly popular in works of fiction as well as with scientific articles. While the term "electronic publishing" is primarily used today to refer to the current offerings of online and web-based publishers, the term has a history of being used to describe the development of new forms of production, distribution, and user interaction in regard to computer-based production of text and other interactive media.

Medical Journals

In 1665 the Royal Society in England published one of the first 2 scientific journals in the world named as the "Philosophical Transactions of the Royal Society." The other was the "Journal des Savants" (Scholars) which appeared in France the same year.

From these 2 journals are descended the many thousands of scientific periodicals today, including all those devoted to the biomedical sciences and medicine, whether they be in print or newer media such as on CD or the Internet.

The original purpose of scientific and medical journals was to permit scientists and physicians to communicate with one another. A newer aim is to permit scientists and physicians to communicate with people who may not be trained as scientists or physicians -- to communicate with the world at large.

Online journals/E-journals

Electronic journals are also known as e-journals. E-journals and electronic serials are scholarly journals or intellectual magazines that can be accessed via electronic transmission.

In practice this means that they are usually published on the Web.

E-journals are a specialized form of electronic document. They have the purpose of providing material for academic research and study, and they are formatted approximately like journal articles in traditional printed journals.

Being in electronic form, articles sometimes contain metadata that can be entered into specialized databases, such as DOAJ (Directory of Open Access Journals) or OAIS (Open Archival Information System) as well as the databases and search-engines for the academic discipline concerned.

Some electronic journals are online-only journals; some are online versions of printed journals, and some consist of the online equivalent of a printed journal, but with additional online-only (sometimes video and interactive media) material.

Most electronic journals are published in HTML and / or PDF formats, but some are available in only one of the two formats. A small minority publish in DOC, and a few are starting to add MP3 audio.

Some early electronic journals were first published in ASCII (*American Standard Code for Information Interchange*) text, and some informally published ones continue in that format.

- Most commercial journals are subscription-based, or allow pay-per-view access.
- Many universities subscribe in bulk to packages of electronic journals, so as to provide access to them to their students and faculty. For e.g., HELINET
- It is generally also possible for individuals to purchase an annual subscription to a journal, via the original publisher.
- An increasing number of e-journals are now available as open access journals, requiring no subscription and offering free full-text articles and reviews to all.

- Individual articles from electronic journals will also be found online for free in an ad-hoc manner: in working paper archives; on personal homepages; and in the collections held in institutional repositories and subject repositories.
- Some commercial journals do find ways to offer free materials. They may offer their initial issue or issues free, and then charge thereafter. Some give away their book reviews section for free. Others offer the first few pages of each article for free.

Indexing

Indexing is an index, wherein, a systematic arrangement of entries is designed to enable users to locate information in a document. The process of creating an index is called indexing, and a person who does it is called an indexer.

- An index is a concise, cohesive, and well-interconnected map to the text. It is an essential tool to accessing and revisiting content. It provides references to the locations of important information and deliberately excludes references to irrelevant information.
- There are many types of indexes, including back-of-the-book indexes for nonfiction books, cumulative indexes for journals, and computer database indexes.
- The index for a nonfiction book is typically the responsibility of the author. Most authors don't index their own work and few publishers have in-house indexers. 95 percent of indexing is done by freelancers hired by authors or publishers.
- Indexing is a way that you classify things into a certain type of order.
- Indexing refers to the recording of different things such as names or subjects in an index. It is also used in reference to the act of providing an index to something. An index is a list of items with references to where they occur in a book.
- Indexing is the process of creating indexes for record collections. Having indexes allows researchers to more quickly find records for specific individuals; without them, researchers might have to look through hundreds or thousands of records to locate an individual record.

Medical Subject Headings (MeSH)

Medical Subject Headings is a comprehensive controlled vocabulary for the purpose of indexing journal articles and books in

the life sciences; it can also serve as a thesaurus that facilitates searching. It is created and updated by the United States National Library of Medicine (NLM), and it is used by the MEDLINE/PubMed article database and by NLM's catalog of book holdings.

MeSH was introduced in 1963. The yearly printed version was discontinued in 2007 and MeSH is now available online only. It can be browsed and downloaded free of charge through PubMed. Originally in English, MeSH has been translated into numerous other languages and allows retrieval of documents from different languages.

Indexing tools

There are 15 Indexing tools as follows:

1. Index Medicus / Medline / PubMed
2. Web of Science
3. SCOPUS
4. EMBASE
5. Google Scholar
6. DOAJ: Directory of Open Access Journals
7. Index Copernicus
8. WHO-HINARI
9. CAS (chemical Abstract Services)
10. BIREME Virtual Health Library
11. Indian Sciences Abstracts
12. Journal Seek Database.
13. CIRS (International Center for Scientific Research) Database.
14. H-index
15. IndMed

Index Medicus

Index Medicus (IM) is a comprehensive index of medical scientific journal articles, published since 1879. It was initiated by John Shaw Billings, Head of the Library of the Surgeon General's Office, United States Army. This library was later evolved into the United States National Library of Medicine (NLM), which continues publication of the *Index*.

Medline

Medline is a bibliographic database of life sciences and biomedical information. It includes bibliographic information for articles from academic journals covering medicine, nursing, pharmacy, dentistry, veterinary medicine and health care. Medline

also covers much of the literature available in biology, and biochemistry, as well as in fields such as molecular evolution.

Medline is freely available on the Internet and searchable via PubMed and NLM's National Center for Biotechnology Information. The subject scope of Medline is biomedicine and health, broadly defined to encompass those areas of the life sciences, behavioral sciences, chemical sciences, and bioengineering needed by health professionals and others engaged in basic research and clinical care, public health, health policy development, or related educational activities.

Medline also includes topics on life sciences that are vital to biomedical practitioners, researchers, and educators. It included aspects of biology, environmental science, marine biology, plant and animal science as well as biophysics and chemistry. Increased coverage of life sciences began in 2000. The majority of the publications covered in Medline are scholarly journals.

PubMed

PubMed is a free database accessing primarily the Medline database of references and abstracts on life sciences and biomedical topics. PubMed is a well-known indexing service of Medical Journals produced by US National Library of Medicine.

The United States National Library of Medicine (NLM) at the National Institutes of Health maintains the database as part of the Entrez system of information retrieval.

Medline is the primary component of PubMed®, part of the Entrez series of databases provided by the NLM National Center for Biotechnology Information (NCBI).

Medline is the primary component of PubMed (http://pubmed.gov); a link to PubMed is found on the NLM home page at http://www.nlm.nih.gov.

Medical Researchers normally start with searching internal indexing services like PubMed

Web of Science

Web of Science was produced by Thomson Reuters (USA) 1961

Access Providers: Various institutions and commercial organizations

Coverage Disciplines: Science, social science, arts, humanities (supports 256 disciplines)

Record depth: citation indexing, author, topic title, subject

keywords, abstract, periodical title, author's address, publication year

Format coverage: full text articles, reviews, editorials, chronologies, abstracts, proceedings (journals and book-based), technical papers

Temporal coverage: 1900 to present

Geospatial coverage: Global – international

Number of records: 40.1 million +

Scopus

Scopus is a bibliographic database containing abstracts and citations for academic journal articles. It covers nearly 21,000 titles from over 5,000 publishers, of which 20,000 are peer-reviewed journals in the scientific, technical, medical, and social sciences (including arts and humanities).

- It is owned by Elsevier and is available online by subscription. Searches in Scopus incorporate searches of scientific web pages through Sciurus, another Elsevier product, as well as patent databases.
- Elsevier is the publisher of Scopus and is also one of the main international publishers of scientific journals,
- Scopus is an independent and international Content Selection and Advisory Board, was established to prevent a potential conflict of interest in the choice of journals to be included in the database, and to maintain an open and transparent content coverage policy, regardless of publisher.
- The board consists of scientists and subject librarians.
- A 2008 study compared PubMed, Scopus, Web of Science, and Google Scholar and concluded PubMed and Google Scholar are accessed for free.
- Scopus offers about 20% more coverage than Web of Science, whereas Google Scholar offers results of inconsistent accuracy.
- PubMed remains an optimal tool in biomedical electronic research. Scopus covers a wider journal range but it is currently limited to recent articles (published after 1995) compared with Web of Science.
- Google Scholar, as for the Web in general, can help in the retrieval of even the most obscure information but its use is marred by inadequate, less often updated, citation information."

Embase

Embase from Elsevier Life Science Solutions is the most comprehensive international biomedical database for biomedical researchers. It enables you to track and retrieve precise information on drugs and diseases from pre-clinical studies to searches on critical toxicological information.

Embase's biomedical database has over 25 million indexed records from thousands of peer-reviewed journals, Embase provides the confidence and tools you need to capture the most relevant and up-to-date biomedical research.

Information managers, regulatory specialists, clinicians, medical librarians, educators and students use Embase for its breadth and depth of data. Embase can help you with everything from clinical trials research to pharmacovigilance

Google Scholar

Google Scholar is a freely accessible web search engine that indexes the full text of scholarly literature across an array of publishing formats and disciplines. It was released in beta in November 2004

Google Scholar index includes most peer-reviewed online journals of Europe and America's largest scholarly publishers, plus scholarly books and other non-peer reviewed journals. It is similar in function to the freely available Sciurus from Elsevier, CiteSeerX, and get CITED. It is also similar to the subscription-based tools, Elsevier's Scopus and Thomson ISI's Web of Science.

DOAJ

The DOAJ was founded in 2003. Its aim is to increase the visibility and ease of use of open access scientific and scholarly journals, thereby promoting their increased usage and impact. The DOAJ is comprehensive and covers all open access scientific and scholarly journals that use a quality control system to guarantee the content. In short, the DOAJ to be the one-stop shop for users of open access journals.

Selection Criteria

Coverage:

Subject: all scientific and scholarly subjects are covered

Types of resources: scientific and scholarly periodicals that publish research or review papers in full text.

Acceptable sources: academic, government, commercial, non-profit private sources are all acceptable.

Level: the target group for included journals should primarily be researchers.

Content: a substantive part of the journal should consist of research papers. All content should be available in full text and all languages

Quality: For a journal to be included it should exercise quality control on submitted papers through an editor, editorial board and/or a peer-review system.

Index Copernicus

Index Copernicus (IC) is an online database of user-contributed information, including scientist profiles, as well as of scientific institutions, publications and projects established in 1999 in Poland.

The database has several productivity assessments tools which allow to track the impact of scientific works and publications, individual scientists, or research institutions. In addition to the productivity aspects, the Index Copernicus also offers the traditional abstracting and indexing of scientific publications. The database is operated by Index Copernicus International.

WHO-HINARI

HINARI Programme has been set up by World Health Organization (WHO) together with major publishers. It enables low- and middle- income countries to gain access to one of the world's largest collections of biomedical and health literature. Up to 13,000 journals (in 30 different languages), up to 28,800 e-books, up to 70 other information resources are now available to health institutions in more than 100 countries.

Areas and territories that are benefitted by HINARI program are many thousands of health workers and researchers, who in turn, contribute to improve world health.

Chemical Abstracts Service (CAS)

Chemical Abstracts Service (www.cas.org**), a division of the American Chemical** Society, is the World's authority for chemical information.

CAS is the only organization in the world whose objective is to find, collect and organize all publicly disclosed chemical substance information. A team of scientists worldwide curates and controls the quality of the databases, which are recognized as the most comprehensive and authoritative by organizations around the world.

By combining these databases with advanced search and

analysis technologies (SciFinder® and STN®), CAS delivers the most current, complete, secure and interlinked digital information environment for scientific discovery.

BIREME- Virtual Health Library

The Latin American and Caribbean Center on Health Sciences Information or BIREME was founded in Brazil in 1967 as the Bibliotheca Regional de Medicina (Regional Library of Medicine, hence the acronym),

It is a specialized center of the Pan-American Health Organization (PAHO) / World Health Organization (WHO). BIREME coordinates the model development of the *Virtual Health Library* which includes around 20 million references for the access to the scientific and technical literature of the Latin America and Caribbean region.

Indian Science Abstracts (ISA)

Indian Science Abstracts (ISA) is a semi-monthly abstracting journal which has been reporting scientific work done in India since 1965.

Original research articles short communications, review articles, and informative articles published in current scientific and technical periodicals, proceedings of conferences and symposia, monographs and other publications, as well as patents, standards and theses are reported in ISA.

International Center for Scientific Research (CIRS)

CIRS was created on 17th of October 1998 in France. The International Center for Scientific Research is an international scientific organization, created to foster and promote all aspects of science and scientific research. In 1999, the CIRS created aninternet portal of scientific websites, that has since become a valuable worldwide reference. The totality of the information offered in the CIRS websites is freely accessible, according to its ethics and its mission.

h-Index

H-index was suggested by Jorge E. Hirsch, a physicist at UCSD, as a tool for determining theoretical physicists' relative quality and is sometimes called the Hirsch index or Hirsch number.

The h-index is an index that attempts to measure both the productivity and impact of the published work of a scientist or scholar. The index is based on the set of the scientist's most cited papers and the number of citations that they have received in other

publications. The index can also be applied to the productivity and impact of a group of scientists, such as a department or university or country, as well as a scholarly journal. The index can also be applied to the productivity and impact of a group of scientists, departments or universities or countries.

The *h*-index is an index that quantifies both the actual scientific productivity and the apparent scientific impact of a scientist. The index is based on the set of the scientist's most cited papers and the number of citations that they have received in other publications.

IndMED

IndMED is a database covering prominent peer reviewed Indian biomedical journals.

- Database is designed to provide medical professionals/researchers/students and the medical library professional quick and easy access to Indian literature.

  Bibliographical databases, also known as indexing and abstracting services - are the first-line tools used by researchers for literature survey. IndMED aims to supplement the literature surveys with Indian references. Moreover, it would be of immense use for researchers on diseases and medical problems more prevalent in India than in other developed countries.

MedIND

Indian medical community produce half the number of the articles published from the third world, yet only two percent of the papers get noticed by international medical community.

Poorly developed Indian medical journal publishing industry is also responsible for the poor visibility of research published from India. Most journals are society journals. They seldom have overseas subscription agents for distributing journals. This results in very poor circulation of Indian journals overseas.

- It has been shown time and again that better online exposure leads to appreciation and citations to articles. MedIND aims to provide online exposure to those indexed Indian medical journals willing to provide free full text access to their articles.

Peer review and acceptance

Peer review is the accepted method for ensuring that information is of the highest quality and as objective as possible. Articles in peer reviewed or refereed journals are critically assessed

by other experts or scholars in the field before being accepted for publication.

Citation index

- A citation index is a kind of bibliographic database, an index of citations between publications, allowing the user to easily establish which later documents cite and which earlier documents.
- A form of citation index was first found in 12th-century Hebrew religious literature.
- Legal citation indexes were found in the 18th century and were made popular by citators such as Shepard's Citations (1873).
- In 1960, Eugene Garfield's Institute for Scientific Information (ISI) introduced the first citation index for papers published in academic journals, first the Science Citation Index (SCI), and later the Social Sciences Citation Index (SSCI) and the Arts and Humanities Citation Index (AHCI).
- The first automated citation indexing was done by CiteSeer in 1997. Other sources for such data include Google Scholar
- Various components of the citation index such as citation index and its subparts (anonymous and patent cited index), source index, perm term subject index, corporate index along with its sub-parts (geographic and organization index) and journal citation report.
- The structure, working, arrangement of these components of citation index gives a clear idea about all these aspects.
- Citing and cited half-life are calculated and derived for a journal to understand the functioning and value of half-life of a journal.
- Functions of citation index are discussed to understand the various applications of research indicators and research trends in the subjects.

Reasons for classical journal Publishing

Aims & Scope	Content of paper matches with Journal's Aims & Scope
Peer-Review	All papers undergo a rigorous peer-review process prior to Publication
Citation Index	Journal is listed by ISI in the Citation Index
Impact Factor	The Impact Factor of the Journal is high
Competent Editors	Editors (and Referees) are of high scientific standing

Fast Publication	The review and publication process is fast (few months)
High Dissemination	The Journal is international and well spread amongst colleagues
Accessibility	The Journal is also accessible online (on the web)
Free Publication	No charges for authors for publication and/or colour illustrations
Competent Publisher	Publisher is strong in marketing & promotion

Criticism against classical journal publishing

Publication Process too long	The review, typesetting & editing and production processes are too long ("old" technologies and subscription regulations)
Publication charges too high	Normal: High subscription rates : High page charges, high extra charges for colour illustrations and high subscription charges ("old" technologies and optimizing incomes)
Decreasing Dissemination	Decrease in subscriptions by 2-10% per year. Total abort of subscriptions by universities and institutions
Copyright	Prevents free distribution of scientific information , even for scientific purposes
No Open-Access	Even electronic copy of journal only free for subscribers or payment online

Impact factors

- A journal impact factor helps you evaluate the importance of a journal compared to others in a field.
- It is intended to measure how often, on average, authors cite moderately recent articles from that journal.
- The database *Journal Citation Reports (JCR)* uses citation data to compare the more heavily cited peer reviewed journals.
- *JCR* covers the sciences and social sciences from 1999 onwards.

Journal Impact factors

- Journal Impact Factor (JIF) is a measure reflecting the average number of citations to articles published in journals, books, patent document, thesis, project reports, newspapers, conference/ seminar proceedings, documents published in internet, notes and any other approved documents.

- It measures the relative importance of a journal within its field, with journals of higher journal impact factors deemed to be more important than those with lower ones.
- Journal Impact factors are calculated in yearly/half- yearly/ Quarterly/Monthly frequencies for those journals that are indexed in Journal Reference Reports (JRR).

Research Gate Scores

- Research Gate is a social networking site for scientists and researchers to share papers, ask and answer questions, and find collaborators.
- Research gate, as a relatively new and growing scientific network of scientists.
- Nowadays even tags discussion contributions by the size of the newly developed RG score and journal impact factors.
- As if the correct opinion of a person with an "RG score" of 10 counts less than the opinion of a RG superstar with an RG score of, say, 40 or more.

Conclusion

- Impetus for research and scientific writing in the field of medical sciences is the need of hour.
- Encouragement for systematic documentation of clinical materials available in the hospitals and to be used by the interns and post graduate students.
- Periodical orientation / sensitization programs in the form of CME's and workshops are to be conducted among the medical students, teachers and practitioners promoting the skills of scientific writing and publications in the indexed journals indexed in PubMed or Indmed for academic necessary recognitions particularly from Medical Council of India.
- In this direction RGUHS is providing core scholarly internationals journals with good impact factors under its HELINET Consortium with round-the-clock access at every health science institutions in the state of Karnataka affiliated to the University.
- Over one million articles are being downloaded per year from the scholarly journals provided under the consortium by its students, teachers and researchers of the affiliated institutions.
- Extensive medical research and publications leads to advancement of knowledge helps to preventive, promotive and curative aspects of health care system.

Publication ethics

Ranjan Kumar Pejaver

Science progresses mainly due to ongoing research. In medical field the thirst for knowledge, keenness to go deeper into a topic, search for causes of diseases, develop treatment modalities, formulate comprehensive management plans and create awareness keeps continuing. The most important aspect is to share this knowledge, discuss the experience, formulate protocols and continue the thought process. This can be done by publishing our work, thoughts and experience. During earlier days, it was through journals available as printed material but now a new area of e –journals available on the net has emerged. In academic circles the evaluation of one's performance and promotion is also linked to publications. Good publications generate revenue and also may lead to further grants needed for research activities.

It is important to realize that publications are read, referred, quoted and followed. Hence it is the duty and responsibility of authors and editors to maintain quality, honesty and transparency in the material published. This aspect can be called as **Publication Ethics.**

Authorship

Authorship tells us as to who did the work of a given research project or who is expressing the knowledge, experience and opinion contained in the publication. It is important that the right people get the credit. At the same time the authors take responsibility to whatever that has been published. Authorship should be based on substantial contribution to conception, design, acquisition of data, its interpretation, analysis and revising it critically.

Violation of authorship occurs as a result of putting down names of people who took little or no part in the research. This means that authorship has been ***gifted!*** Also, by leaving names of people who did take part in a significant manner. This is called ***ghost authorship***! Many journals have limitation of the number of authors depending on the category of the article. Ex; case reports cannot have more than 5 authors etc.

Guidelines

The International Council of Medical Journal Editors (ICMJE) now has issued guidelines about authorship. It is recommended that at the time of submission, it should be clearly stated and even described regarding contributions made by each author and preferably the editor publishes the information. Corresponding author also has an administrative role, and usually involves a senior person and readers should be able to communicate easily with the person. First author is the main person involved with the work done and most credit worthy as the publication is always referred with this name e.g. Smith *et al* etc. Guarantor is the person who will vouch and take responsibility for the integrity of the entire project from inception to printing of the same. Editor usually refers to him for technical details of the publication.

There is a scope to acknowledge a person's contribution who may not be able to merit an authorship of the article. However, journals will have their own definitions for the same and may impose restrictions.

Submission of Publication

It is of utmost importance that a manuscript is not submitted to more than one journal at the same time. Editors do not take this lightly as it is a serious malpractice if it appears in more than one journal. It causes immense difficulties when the article is withdrawn at the last minute when the process of peer review, revision and proofing has been completed. ***Redundant publication*** occurs when more than one paper is submitted to different sources which share the same data from a given project, have similar discussion points and conclusions. At times articles presented at a conference and appeared as abstracts in the proceedings are submitted again as article to journals. This may amount to re-publication. However, a complete and prominent disclosure of its original source at the time of submission will enable the editor to take a decision. The same applies to submission of an article already published in a journal of different specialty or another language.

Plagiarism

Unreferenced use of others published and unpublished data, ideas and manuscript is termed as Plagiarism. Submission of a full paper or part under new authorship, sometimes in different languages is also not allowed. Please remember that this can occur at any stage of planning, research or writing. It applies to both print and electronic versions. It is very important that all sources of references,

figures and photos should be disclosed if necessary, permissions sought and the permission letter sent to the editor.

Several plagiarism detection tools are now available to the editor. It is possible to compare authored work against content in the database of several journals and books. Editor could highlight a text and match for similar text in other sources. **Ultimately it is the honesty, integrity and credibility of the author that is relied upon by the editor.**

Conflict of Interest

A person has a conflict of interest when he or she has an attribute that is ***invisible*** to the reader or editor but which ***may*** affect his or her judgement. Conflict of interest may be personal, commercial, political, academic or financial. There is lots of room for arguing over the degree of overlap and what's legitimate. Always declare a conflict of interest, particularly one that would embarrass you if it came out afterwards. Disclosure is the key. Send copies of overlapping papers and reference them. The problem is not the publication but the lack of disclosure. Hence, where relevant, conflict of interest must be declared. If in doubt, disclose and the editor will take a call on that. Please note that in some instances the term 'competing interest ' is used which means the same.

Dealing with misconduct

Confirming misconduct is Intention to cause others to regard as true that which is not true. It deals not only on the particular act or omission, but also on the **intention** of the researcher, or author. Several actions may be taken. Alert the employers of the accused author(s). Be referred to the local/national Medical Council. There are several organizations which will speak more on this topic and guide an author.

The **Committee on Publication Ethics** (COPE) has published guideline on good publication ethics.Available free at ***www.publication ethics.org.uk.*** Council for International Organizations of Medical Sciences (CIOMS), International Committee of Medical Journal Editors (ICMJE),Nuffield Council on Bioethics are some of the other useful contacts.

Authorship

P. S. Shankar

A scientific article or a book may be written by a single individual as author or many persons may collaborate to produce the work. When many joins together in the writing, one may not write, but contribute substantially in the conception of the work or the analysis of the data. When many persons located at different places in the country or abroad work together and they are considered as co-authors. However, when many authors work closely with individuals located in different places, it becomes difficult to differentiate between an 'author' and a 'contributor

The International Committee of Medical Journal Editors (ICMJE) has formulated a set of guidelines to define authorship (1). A contributor may be considered as an author if he/she meets the following criteria

1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work,
2. Drafting the work or revising it critically for important intellectual content,
3. Final approval of the version to be published, and
4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (2).

Due to the advances in communication, it has become possible to undertaking research projects by sharing information and collaboration with persons in different parts of the country and different countries.

It has resulted in an increased number of collaborators and co-authors in scientific writing. It has resulted in difficulty to differentiate between a 'contributor' and an 'author'.

By following ICMJE definition, it is possible to identify the persons who are chiefly responsible for the academic work.

Earlier it was common to the articles written by a single author. Now the scientific articles are prepared through collaborative effort of many individuals. It has necessitated to create a hierarchy among the many people involved in the production of the scientific article.

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Plagiarism

K Karthikeyan

Introduction

Scientific publication over the years has seen many advances with thousands of articles published by the journals. The publication of a scientific article involves essence of good medical writing, or for that matter, any kind of scientific writing, is a clear, concise, accurate, and honest presentation of the scientific idea. The pressure to publish, the tight time frame and lack of innovation or writing skills results in unethical practice in medical writing. The Office of Research Integrity (ORI), USA, defines research misconduct as 'fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results. One such common unethical practice is called as plagiarism.

Definition

The use of the word "plagiarism" in the English language dates back to the 16th century. It is derived from the Latin word *"plagiare"* which means to "kidnap" There are several definitions for plagiarism.

The World Association of Medical Editors (WAME) defines plagiarism as "the use of others' published and unpublished ideas or words (or other intellectual property) without attribution or permission, and presenting them as new and original rather than derived from an existing source."

The Office of Research Integrity, USA, defines research misconduct as "fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results. 'In simple words plagiarism is a scientific theft.

Types

Plagiarism is not merely copying text. It is actually stealing matter or ideas from others without giving credit to them. It must be remembered plagiarism is just confined to textual content but that using published photos, images, art work, and tables without written permission is also plagiarism. Plagiarism is of many types.

Plagiarism has many forms such as blatant plagiarism, technical plagiarism, patchwork plagiarism, and self-plagiarism. Plagiarism in any form is a threat to the research integrity and is an offence.

Blatant plagiarism is an act in which the author tries to deceive the reader into believing that he/she is totally responsible for the scientific content of the research work. Technical plagiarism is when author is not trying to cheat or deceive the reader but fails to follow the accepted methods of using and revealing sources. Patchwork plagiarism also known as mosaic writing is taking text portion from several sources, combining them, and presenting the resulting text as one's own work.Patchwork plagiarism is very common and difficult torecognize because of its complexity and ability to pass through the plagiarism detection software. Another form of plagiarism is self-plagiarism, which means borrowing or using words as a large portion of the present work from one of his/her previously published article. Many authors tend to think that copying from one's own previously published writing is acceptable. However, self-plagiarism is also a plagiarism and should be treated as one. Self-plagiarism has four subtypes:

Duplicate publication

Duplicate (redundant) publication: It occurs when an author submits identical or almost identical manuscripts to two different journals for publication. In this case the author hopes for a positive response from at least one of the journals. Nowadays the author has to give an undertaking at the time of sending the manuscript that the article has not been sent to any other journal.

Augmented publication

Augmented publication: In this case the authors add additional data to already published data and submit the new manuscript with new, recalculated results often with different title and adjusted study aims. Here the author may also falsify the results and other tables so that they do not resemble the original article.This type of plagiarism is difficult to detect.

Segmented publication

Segmented (salami) publication: It occurs when two or more papers are derived from the same experiment. This is very common where one study is bifurcated for the purpose of number. The authors may write different articles from the same study and the population. This form of plagiarism is also difficult to detect.

Text recycling

Text recycling: Many authors publish on the same subject or do research work on the same population. They use large portion of one's own already published work in their new manuscript. This type of plagiarism and is easily detectable by plagiarism detection tools and software.

Ethical code

Researchers and authors of scholarly papers should follow ethical code of good scientific practice, based on the principles of honesty and integrity. Paraphrase and summary are the two most important ways to avoid plagiarism. Paraphrase means to express someone else's ideas in your own language and to summarize means to write down the essence of someone else's work. The common methods to be adopted to avoid plagiarism are:

1. Always acknowledge and quote the original source of idea, text, pictures, artwork, or illustration right below it.
2. The text-copied verbatim from any source must be enclosed within quotation marks. This should be stated in the article.
3. Even when paraphrasing has been carried out, it is essential to properly acknowledge the original source.
4. If part of the own previous publication is used in the research work, it must be clearly disclosed in the covering letter to editor. It should be done to avoid being penalized for plagiarism.
5. Always obtain a prior preferably written permission is required to use any published table, figure, picture, artwork.
6. If one feels that he/she has used somebody else's idea or text unintentionally without appropriate referencing, one should immediately write to the journal editor and seek advice.
7. The last but not the least before submission, run your manuscript through plagiarism check websites to avoid the embarrassment of being caught plagiarizing later.

Retraction

If the plagiarism is detected after publication the editors should analyze the published paper and decide whether a corrected article needs to be published or retraction is required. If retraction is necessary, it should be linked to the article through Medline in such a way that no electronic search can reach the unrestricted form of the article.

Eliminating plagiarism is a biggest challenge facing the scientific research. It requires a consorted effort on the part of the authors so that they do not commit this scientific fraud.

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Retraction

P S Shankar

The word 'retraction' in scientific publications means permanent withdrawal, cancellation or reversal of the earlier statement and withdrawal of a paper from the academic journal. This can be done by the editor(s) of the journal or by the author(s) of the papers or even their institution. There need not be any further explanation by the author. Online journals undertake such a process by removing the article from online access.

The number of papers retracted for fraud have shown an increase in the recent years (1). The increase reflects that the journals are more vigilant in verifying the scientific literature. A retraction happens to be a last resort for the medical/scientific journals. It implies that the results are no longer trustworthy and are beyond correction.

There is a website called 'Retraction Watch', which not only publishes the retractions but also goes to the people involved to get their explanation on the matter.

Retractions may occur under the following categories

1. Error
2. Fraud or misconduct
3. Data provenance
4. Public issues

*1.**Retraction due to error:***

It is a common belief that Mediterranean diet consisting of fruits, vegetables, olive oil, nuts and fish is a healthy diet. Though research has suggested people who eat such a diet to be healthier, but it is difficult to prove whether it is due to the diet or some other factors.

An article appeared in *New England Journal of Medicine* in 2013 giving some proof to the above contention. The article had stated that people eating the Mediterranean diet with supplements of olive oil appeared 30 percent less likely to experience a heart attack, stroke or death from cardiovascular causes than people on a low-fat diet. The

journal retracted the paper due to the problems in the manner the study was undertaken. Later this paper was replaced by a corrected version showing that people following the diet had shown a reduced level of heart attack and strokes.

Errors involve in data collection or classification, statistical analysis or information that is unverifiable by the reviewers.

2. *Retraction for fraud or misconduct*

Misconduct is considered when there is simultaneous submission to multiple journals, conflicts of interest, fabrication or manipulation of data, failure to comply with research protocols, or plagiarism.

Haruko Obokata, a young Japanese post-doctoral stem cell researcher, working at Riken Center for Developmental Biology, at Kobe, Japan, achieved international recognition and fame following publication of two path breaking original articles in *Nature* on January 30, 2014. The Japanese daily *Asahi Shimbun* in its editorial hailed the event, and wrote 'a brilliant new star has emerged in the science world.' Further it wrote that it is a major discovery that could rewrite science textbooks. It was hailed as one of the great scientific breakthroughs of the twenty first century.

Soon there was lot of controversy that made enquiries about the details of the fundamental mechanism of the research undertaken by her. Unable to provide a satisfactory explanation she retracted on June 4, 2014 the first paper published, and a week later the second paper. The Institute where she was working announced that both articles have been retracted.

Stem cells are classified based on their developmental versatility. Embryonic stem cells are capable of making any cell in the body, hence pluripotent. Adult stem cells can produce only cells appropriate to their native tissue.

Researchers have hoped that a cell can reprogram itself under certain conditions and produce unexpected cell types.

Obokata and her colleagues,Teruhiko Wakayama, YoshikiSasai, Koji Kojima, Martin P Vacanti, Hitoshi Niwa, Masayuki Yamato and Charles A Vacanti, had demonstrated in their study ordinary adult cells can be reversed into pleuripotent stems cells when submerged in a solution of adenosine triphosphate (ATP), a cellular fuel that is mildly acidic.

This appeared to be simple turning ordinary cells into stem

cells by subjecting them to profound stress. The stress of acid acted as a stimulus for the cells to acquire pluripotency, and the cells are referred to as stimulus triggered acquisition of pluripotency (STAP) cells. Here the acid stress had killed most cells, but the survivors sustained by ATP flourished. These cells were shown to be better suited than embryonic stem cells. The embryonic stem cells are capable of forming only embryonic cells. But the STAP cells possessed the ability to form both embryonic and placental tissue.

The formation of the STAP cells was questioned. Reproducibility is an essential step in scientific progress. There was intense scrutiny and growing doubt about the validity. Genetic tests undertaken on 20 stem cell lines including the cells used in the study of Obokata failed to match the mouse from which the adult cells were obtained. This made Prof Vacanti to withdraw the paper. The results obtained by Obokata could not be replicated within a short period following publication of the paper. It was concluded that results are duplication of text and manipulation of images. The two images found in the second paper, one purporting to show a placenta made using STAP cells and the other a placenta derived by a contrasting technique appeared almost identical.

Riken center announced that its replication efforts had failed and found evidence of falsification and fabrication offences that constitute research misconduct. There was publication in *Nature* by Daley about STAP which showed failure of attempts made in seven laboratories to validate the claims of Obokata and her colleagues.

3. *Retraction for data provenance*

During the COVID-19 pandemic, based on a database of COVID-19 patients, an article appeared in the *Lancet* on 22 May 2020, it was titled 'Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis.' The authors had stated that hydroxychloroquine and chloroquine increase the chance of patients dying in hospital and increase the chances of ventricular arrhythmias (2). Concerns were raised with respect to the veracity of the data and analyses conducted by Surgisphere Corporation, Chicago. The authors were Mandeep R Mehra, Sapan S Desai, Frank Ruschitzka and Amit N Patel. Medical researchers and newspapers, and expressed suspicions about the validity of the data.

The Lancet organised an independent third-party peer review to evaluate the origination of the database elements, to confirm the

completeness of the database, and to replicate the analyses presented in the paper. However, the Surgisphere failed to transfer the full dataset, client contracts, and the full ISO report of their servers for analysis. The reviewers could not carry out an independent and private peer review. The journal found that it can no longer vouch for the veracity of the primary data sources. The authors on 4 June 2020, requested that the paper be retracted. They apologised for any embarrassment or inconvenience that may have caused.

New England Journal of Medicine had published an article of Mehra MR and colleagues on Cardiovascular disease, drug therapy and mortality in Covid-19. Following the publication, hundreds of scientists raised questions about the provenance of Surgisphere's dataset. Immediately the journal issued its own retraction. The authors stated 'Because all the authors were not granted access to the raw data and the raw data could not be made available to a third-party auditor, we are unable to validate the primary data sources underlying our article. We therefore request the article be retracted. We apologize to the editors and to readers of the Journal for the difficulties that this has caused.'

4.*Retraction over public issues*

An article on the functioning of the human hand, appeared on March 4, 2016 in PLOS ONE under Blog Series 'Faith and Science seeking understanding: Reviewing Creator gate'. It was retracted due to outrage on social media over a reference to 'Creator'.

According to Elsevier. A retraction note should be titled "Retraction: [article title]" signed by the authors and/or the editor is published in the paginated part of a subsequent issue of the journal and listed in the contents list. A link is created to the original article in the electronic version. The online article is preceded by a screen containing the retraction note.

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Expressions of Concern

P.S. Shankar

There are occasions when the editor of the Journal may issue an Expression of Concern if the article that has been published in the journal carries well-founded concerns and he feels that readers should be made aware of potentially misleading information mentioned in the article.

It must be noted the Expressions of Concern is issued if an investigation into the problems relating to the article is not completed, and if there exist strong indicators that the concerns are valid.

Rarely an Expression of Concern may be issued even when the investigation is in progress, pending the judgment that is available after some time. In such an unusual situation there must be valid reasons.

An Expression of Concern is associated with the same risks to the reputation of the researcher as a retraction. In many instances, the editor waits for a definitive judgement by an independent investigation.

After publication of an article by Mehra and colleagues on 'Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis' in *the Lancet* on May 22, 2020, many scientific questions were raised about the data reported in the paper (1). Though an independent audit of the provenance and validity of the data was commissioned by the authors not affiliated with Surgisphere, and the investigation was in progress, with results expected shortly, the journal issued an Expression of Concern to alert the readers about serious scientific questions that had been brought to their attention. Further it was mentioned that they will update this notice as soon as further information is available (2).

On May 1, 2020 a paper on “Cardiovascular Disease, Drug

Therapy, and Mortality in Covid-19" was published (3). It was a study to determine the effect of pre-existing treatment with angiotensin-converting enzyme (ACE) inhibitors and angiotensin-receptor blockers (ARBs) on Covid-19. For this retrospective study the authors used data drawn from an international database that included electronic health records from 169 hospitals on three continents. Following its publication lot of concerns were raised about the quality of the information in that database. *The New England Journal of Medicine*, asked the authors to provide evidence that the data are reliable. In the interim and for the benefit of the readers of the journal, the Editor published an Expression of Concern about the reliability of conclusions made in the study (4).

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