SCIENTIFIC MEDICAL RESEARCH

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LECTURE: 17-19

22.11 Meta-Analysis

Meta-analysis (tertiary analysis) **combines into one summary statistic the results of several high-quality quantitative studies that used similar methods to collect and analyze their data.** The inclusion criteria for meta-analyses are usually more restrictive than they are for general systematic reviews; so systemic review and meta-analysis are separated procedures!

The meta-analysis process:

- **Use a systemic search strategy to identify relevant articles.**
- **Carefully read each study.**
- **Assess the quality and comparability of each study.**
- **Extract statistical results from each of the eligible studies.**
- **Combine comparable statistical results into one summary statistic.**

22.12 Pooled Analysis

Homogeneous (similar) studies can be combined into a summary statistic, but caution should be used if the studies are heterogeneous (dissimilar).

The amount of variability in the measure between studies can be examined using a Cochran's Q statistic for homogeneity and the I^2 statistic.

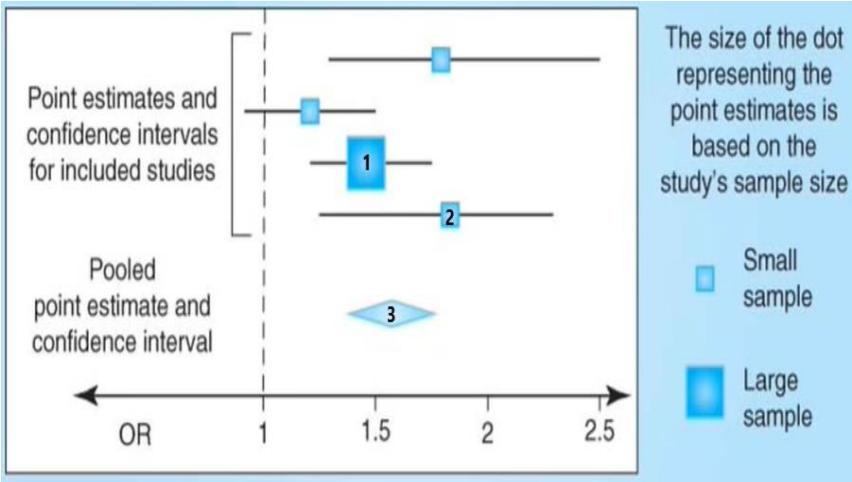
- There are two main choices of models to use for meta-analysis:

1. **A <u>fixed effects model</u> can be used to create a pooled estimate when the studies are fairly homogeneous.** (There is little variability)
2. **A <u>random effects model</u> is required when the tests of heterogeneity show that the included studies are dissimilar.** (There is considerable variability)

** The results from studies using different study designs, different interventions, or dissimilar population groups should not be pooled

22.13 Forest plots and funnel plots

A forest plot displays the contributing studies and the summary measure for a meta-analysis. >>>>>>>>>



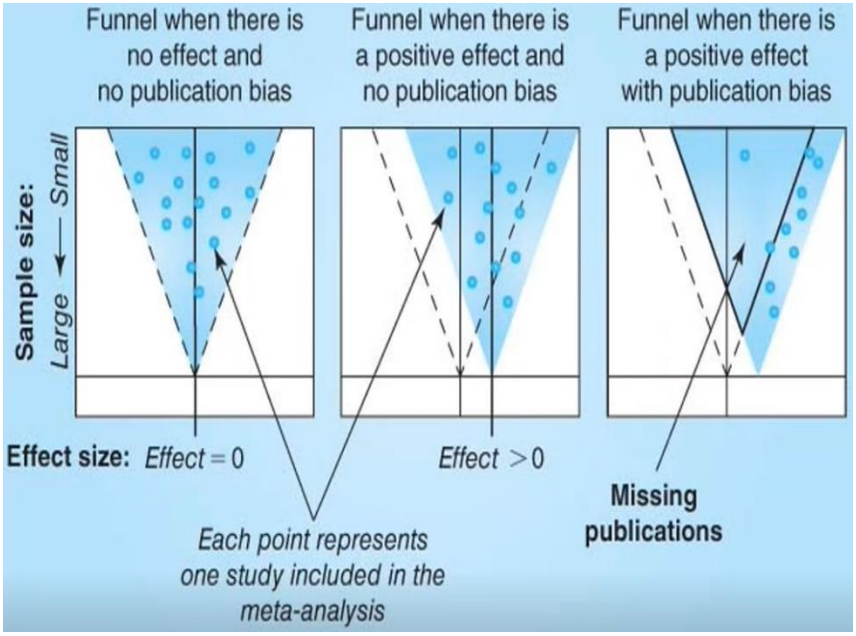
Effect size is the magnitude of the difference in the value of a statistic in independent populations. Many types of statistics can quantify effect sizes, including **odds ratios (OR),** difference in means measures…

Each square represents a different study whose sample size is represented by the size of the square; [2] is smaller but more risk than [1].

[3] A diamond shape represents what the potential risk collectively based on all those studies (the sum of their results).

A funnel plot visually displays the likelihood of studies missing from the analysis because of publication bias. >>>>>>>>>

If no publication bias has occurred, the points for the included studies will form a triangle. If publication bias has reduced the number of publications with statistically insignificant results, part of the triangle will be missing. In that situation, the pooled estimate is likely to have overestimated the true effect size.



History of clinical research and its ethics:

Here are some recent events in medical research that formed and shaped our current guidelines, regulations and system:

1932–1972: Tuskegee Syphilis Study

The most notorious example in the United States of prolonged and knowing violations of the rights of a vulnerable group of research participants.

That study, conducted under the auspices of the U.S. Public Health Service (PHS) at Tuskegee Institute (now Tuskegee University) in Tuskegee, Alabama, was originally projected to last six months but spanned 40 years—from 1932 to 1972. The purpose of the study was to determine the effect of untreated syphilis in black men. The men in the study were never told that they had syphilis.

This research used disadvantaged, rural black men to study the course of an untreated disease.

The men were offered free examinations and medical care but were not informed of their disease, that they were participating in research, or that the research would not benefit them.

Further, in order not to interrupt the project, participants were deprived of demonstrably effective treatment long after such treatment was discovered and had become generally available.

1939–1945: Nazi Experiments During World War II

Although not the first example of harmful research on unwilling human participants, the experiments conducted by Nazi physicians during World War II were unprecedented in their scope and the degree of harm and suffering to which human beings were subjected.

"Medical experiments" were performed on thousands of concentration camp prisoners and included deadly studies and tortures such as injecting people with gasoline and live viruses, immersing people in ice water, and forcing people to ingest poisons.

In December 1946, 23 physicians and administrators, many of them leading members of the German medical hierarchy, were indicted before the War Crimes Tribunal at Nuremberg for their willing participation in the systematic torture, mutilation, and killing of prisoners in experiments.

Despite the arguments of the German physicians that the experiments were **medically justified**, the Nuremberg Military Tribunals condemned the experiments as "crimes against humanity"; 16 of the 23 physicians were found guilty and imprisoned, and 7 were sentenced to death. In the August 1947 v, the judges included a section called "Permissible Medical Experiments." This section became known as the Nuremberg Code and has formed the basis for ethics codes internationally.

1963: The Willowbrook Study

From 1963 to 1966, studies were carried out at Willowbrook State School, a New York institution for "mentally defective persons."

These studies were designed to gain an understanding of the natural history of infectious hepatitis and, subsequently, to test the effects of gamma globulin in preventing or ameliorating the disease.

The participants, all children, were deliberately infected with the hepatitis virus. Early participants were fed the stools of infected persons. Later, subjects received injections of more-purified virus preparations.

Researchers defended the deliberate injection of these children by noting that the majority would acquire the disease anyway while at Willowbrook, adding that perhaps it would be better for them to be infected under controlled research conditions.

During the course of these studies, Willowbrook closed its doors to new inmates, claiming overcrowded conditions. However, the hepatitis program was able to continue to admit new patients because it occupied its own space at the institution.

Thus, in some cases, parents found they were unable to admit their children to Willowbrook unless they agreed to their participation in the studies.

23.1 Foundations of Research Ethics

- **Nuremburg Code (1947): mandated voluntary consent for experimental studies of humans.**
- **Declaration of Helsinki (1964): written by the World Medical Association to provide guidelines for physicians conducting clinical trials,** and outline the principles of recruiting and involvement humans in researches that require interventions.
- **Belmont Report (1979): published by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to define key research principles and is a foundational document for the current U.S. federal policy for protecting human research participants (the Common Rule).**

** All patient protection regulations, such as the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in the United States, must be strictly adhered to for observational as well as experimental studies.

23.2 Respect, Beneficence, and Justice

- **<u>Respect</u> for persons is a broad concept that emphasizes informed consent, voluntariness, and autonomy** (only an individual is authorized to decide whether to volunteer to participate in a research study)**.**

- **<u>Beneficence</u> means that the study should do good; <u>nonmaleficence</u> means that should do no harm.**

- **Distributive justice seeks to ensure that the benefits and burdens of research are equitable.**

- Questions that can be asked for community-based projects to complement key questions associated with individual-focused projects:

FIGURE 17-2 Sample Ethical Considerations for Individual- and Community-Based Research Projects

	Individual Participants	Community Participants
Respect	▪ What steps have been taken to protect individual rights? ▪ Has the risk of coercion in recruitment been considered and minimized? ▪ Is the informed consent process more than just signing a piece of paper? ▪ Do participants in sensitive studies have privacy? Will their participation be kept secret? ▪ Will data shared with the researchers be kept confidential? Will files be protected and not shared unless individually identifiable information is removed?	▪ What steps have been taken to ensure that a community's values are respected? ▪ Are appropriate community-based research methods being used? ▪ Have community representatives and a local oversight committee been consulted about the project?
Beneficence	▪ How will individuals benefit from participation? Free services, supplies, or medicines? Free health education? Gifts or money? Contribution to knowledge?	▪ How will a participating community benefit from the research project?
Nonmaleficence	▪ What steps have been taken to minimize physical, psychological, financial, social, and other risks to participants? ▪ Is counseling available for participants in sensitive studies? ▪ Is appropriate reimbursement for travel costs and other expenses being offered?	▪ What steps have been taken to ensure that a community is not burdened by research participation?
Justice	▪ What are the long-term benefits for individual participants? For example, will they gain increased knowledge about their health status? ▪ What will happen to participants after the study is completed? Will the results of the study be shared with them?	▪ What are the long-term benefits of participation to the community? ▪ Will the researchers have an ongoing relationship with the community?

❖ Questions that researchers should ask and answer about their own protocols prior to formal review by an ethics committee:

FIGURE 23-1 Eight Central Considerations ("8 Cs") in Research Ethics

Category	Examples of Questions to Ask
Contribution	• Why is the proposed project important? • How will individuals and/or communities benefit from this study?
Compensation	• Will individuals or communities that participate in the study be offered any form of inducement, reimbursement, or compensation? If so, what will be offered, and is it appropriate? Is the offer so high that it could be seen as coercive or so low that the study could be seen as exploitative? • Are the risks of participation minimal? • How will study-related injuries be handled? • Are the risks and benefits balanced?
Consent	• How will potential participants be informed about the study? • How will consent to participate be documented? • Will a test of comprehension of the informed consent statement be required? • If applicable, how will consent (and possibly assent) be acquired for children and other members of potentially vulnerable populations? • If applicable, will community meetings be held prior to beginning the study?
Confidentiality	• How will the privacy and confidentiality of participants and their personal information be maintained?
Community	• Why is research in the selected population important? • Is the source population appropriate for the goals of the research study? • Will the selection process be fair? • Will the sample size be adequate? • Are potentially vulnerable participants adequately protected? • Has the protocol been adapted to address the cultural expectations of the source population? • If applicable, has the community agreed to participate in this project?
Conflicts of interest	• Who is contributing to the project's finances and/or logistics? • Might potential conflicts of interest inhibit the ability of a researcher to conduct ethical and unbiased research?
Collaborators	• Are all members of the research team adequately trained to conduct ethical research? • What steps will be taken during data collection and analysis to ensure that the protocol and all ethical standards are adhered to by all members of the research team?
Committees	• Which research ethics committee(s) needs to review the project? • If applicable, what community organizations have been consulted about the proposed project?

23.3 Incentives (حوافز) and Coercion (إكراه)

- **The desire to thank participants must be balanced with the need for participation in any research project to be voluntary** (i.e., it is not permissible to exploit people's need for money, but you can give them a little money as a gift; specially if they need transportation or something…

- **Researchers have to be very transparent about what participants will gain from participation in a research study and what they will not gain.**

** Coercion could include social pressure or requests from authority figures that make it difficult for an individual not to agree to enroll in a study.

23.4 Informed Consent Statements

- **Informed Consent Statements provide essential information about research projects to potential research participants so that they can make a thoughtful decision about whether to enroll in a study.**

- **The statement must use clear, simple language that the reader understands.**

FIGURE 23-3 Content for the Informed Consent Statement

Content Area	Description
Research	A definition of "research" and a statement that the study involves research
Purpose	An explanation of the purpose and aims of the research process (except in the rare situations in which that interferes with the research goals)
Participants	A description of how and why certain individuals or communities were invited to participate in the research project and an estimate of the total number of individuals who will be recruited
Procedures	A description of the study procedures (including any physical exams, collection of biological specimens, randomization or blinding processes, interventions, or other procedures that are part of the study protocol) and the expected duration of the individual participant's involvement in the study
Benefits	A description of benefits to participants and/or to society, including a clear explanation of the compensation to be offered or a clear statement that the participant will receive no direct benefits
Risks	A description of the possible risks, discomforts, and costs associated with participation, a statement that involvement in the project may involve unforeseeable risks, and a description of how study-related injuries will be handled
Confidentiality	A description of the steps that will be taken to maintain confidentiality
Voluntariness	A statement that participation is voluntary and that the participant may withdraw from the study at any time with no penalty, along with a description for the process of withdrawing from the study
Contact information	Contact information for the researchers
Signature	Space for the participant's signature

23.5 Informed Consent Process

Informed consent is intended to be a process, not merely a piece of paper.

Acquiring a signature is not the end of the process; **the lines of communication between researchers and participants must remain open during and even after the data collection process;** because for any time the participants may decide not to continue and withdraw from the study!

23.6 Informed Consent Documentation

For most research studies, the expectation is that each study participant will sign a printed copy of the informed consent statement.

In a limited number of observational studies (i.e., studies without interventions like cross-sectional studies)**, the full process of acquiring and documenting individual informed consent may not be required.**

- A consent process that does not require a signature may be granted when:
- The responses cannot be linked to individuals.
- The survey instrument does not ask sensitive questions.
- The researchers will not physically examine individuals or collect biological specimens.
- The questionnaire is so short that describing the study would take longer than completing the questionnaire form.
- There are no foreseeable risks to participants.

23.7 Confidentiality and Privacy

- **Privacy: is the assurance that individuals get to choose what information they reveal about themselves.**
- **Confidentiality: is the protection of personal information provided to researchers.**

23.8 Sensitive Issues

Researchers asking questions about sensitive issues must decide ahead of time how to handle disclosures (such as disclosures of participation of illegal activities; drug or alcohol abuse, and sexual practices**).**

The research team can apply for a certificate of confidentiality that protects the identity of participants from being subject to court orders and other legal demands for information.

23.9 Cultural Considerations

A research protocol must be appropriate to the culture or cultures of the expected study participants.

It may be helpful to have a local advisory board facilitate communication between the community and the research team.

23.10 Vulnerable populations

Children and some adults with cognitive impairments may not be considered competent to make an informed decision.

Whenever possible, in addition to having the legal representative's consent, potential participants should assent to their own participation.

23.11 Ethics training and Certification

Research ethics committees usually require everyone who will be in direct contact with research participants and/or their personal data to complete formal research ethics training.

Responsible Conduct of Research (RCR) training programs may also spell out expectations and procedures for disclosing conflicts of interest, avoiding research misconduct, and exhibiting professionalism as researchers.

24.1 Ethics Committee Responsibilities

** **IRB** is a group responsible for protecting people who participate in research studies.

❖ **The three primary goals of Research Ethics Committees (RECs) often called Institutional Review Boards (IRBs), are to:**

1) **Protect the "human subjects" who will participate in research.**
2) **Protect researchers by preventing them from engaging in activities that could cause harm.**
3) **Legally protect the researcher's institution from the liability that could occur as a result of research activities.**

❖ **The major functions of ethics review boards are to:**

- **Review and revised research protocols.**
- **Approve or disapprove those protocols.**
- **Ensure that informed consent is documented (if required).**
- **Conduct continuing review of long-term research projects.**

** An **Institutional Animal Care and Use Committee** (IACUC) oversees research with animals and operates separately from an IRB

24.2 Ethics Committee Composition

Research ethics committees are usually composed of at least five members, preferably from diverse backgrounds, including both scientists and nonscientists (e.g., clergy/sheikh and lawyers)**.**

24.3 Application Materials

Some research ethics committees ask applicants to provide a narrative research statement that addresses a list of possible ethical concerns; others require the completion of dozens of pages of forms.

FIGURE 18-1 Examples of Information Requested and Examined by Ethics Review Committees

Category	Considerations
Participants	■ What is the anticipated composition and size of the study population? ■ Is the source population appropriate for the study question? ■ How will participants be recruited? Does the recruitment method raise any concerns about coercion? ■ What are the inclusion and exclusion criteria? Will the exclusion criteria screen out participants with a higher-than-typical risk of harm? Will the criteria generate a study population that is reasonably representative of the source population? (For example, if the study question applies to all adults, are there any restrictions on participation by reproductive-age women that are not directly related to safety?) ■ If applicable, are potentially vulnerable subjects protected?
Risks and benefits	■ Why is the study important and necessary? How will the proposed study benefit participants and/or their communities? ■ How will data be collected? Will existing data, documents, records, or specimens be used? Will individuals or groups be examined using surveys, interviews, focus groups, or other methods? Will interviews be audio- or video-recorded? Will noninvasive clinical measures be used? Will participants be asked to engage in exercise or tests of endurance, strength, or flexibility? What machines will be used to collect data, and will collection involve radiation exposure? Will blood, hair, nail clippings, sweat, saliva, sputum, skin cells, or other biological specimens be collected noninvasively? Will drugs or devices be tested? ■ What are the potential physical, psychological, financial, or other risks to participants? ■ Are the risks minimal (or at least minimized)? ■ Are the risks reasonable compared to the anticipated benefits?
Informed consent	■ Does the informed consent statement adhere to institutional guidelines? ■ How will informed consent be sought? ■ How will informed consent be documented? ■ Is any modification to the usual methods of documenting informed consent being requested? If so, is the request reasonable? (For example, is a waiver of a signed consent form being requested because the source population has a low literacy rate? Or is a request being made to have no documentation of consent because the existence of a form linking an individual to the study could harm the participant?)
Privacy and confidentiality	■ How will privacy and confidentiality be maintained? ■ What are the plans for the protection of computerized and noncomputerized data?
Safety monitoring	■ What constitutes an adverse event? How will such events be handled? ■ Does the informed consent statement clearly state how research participants can contact the research team and the ethics review board if they have concerns?
Conflicts of interest	■ How is the project being funded? ■ Do any financial or personal conflicts of interest need to be disclosed to participants and/or addressed in other ways?
Researcher training	■ Are the investigators prepared to conduct ethical research?
Documentation	■ Are copies of all recruitment materials attached? ■ Are copies of the questionnaire and other assessment tools attached? ■ Is a copy of the informed consent statement attached? ■ If applicable, are letters of approval from study sites and collaborating institutions attached? ■ If applicable, is a copy of the grant proposal attached? ■ Are copies of research ethics training certificates for all members of the research team attached?

24.4 Review Process

Important!

Once all application materials have been submitted to a research ethics committee, there are three possible next steps:

1) Exemption from review. Exemption can be granted—but does not have to be granted—only after the IRB professionals review a protocol and determine that it meets their criteria for exemption. When a researcher is considering transitioning from a practice-based inquiry (a clinician examining their patients) to an intentional research project (a clinician reviews patient records so that they can be presented as a case series at a professional Conference), the IRB should be consulted about what application materials are required. The decision about whether a practice-based project is exempt from review is up to the IRB, not the researcher.
** Exemption from review is not allowed for research focused on vulnerable populations.

2) Expedited review: is a determination by an IRB that a proposal requires review but a review by the full committee is not required. An expedited review may be possible when a minor change to a previously approved protocol is requested. Sometimes expedited review is also possible for new studies in which the risk to participants is no greater than what is encountered in ordinary daily life or, in the case of clinical work, during routine examinations or procedures.

3) Full review: is a determination by an IRB that the full committee must discuss a study protocol in order to ensure that the requirements for the protection of human subjects are met. Full review of a research proposal is usually required when an intervention will be tested in individuals or a community, data will be collected through interaction with individuals, identifiable private information will be collected, or other criteria for expedited review are not met.

** These decisions are made by research ethics committees (not the researchers themselves).

24.5 Review by Multiple Committees

At least three issues must be resolved prior to submission of a research proposal to multiple committees:

i.e., Some researchers may do research in multiple institutions; so they should meet each institution requirement.

- ✓ **The application documents that will be required.**
- ✓ **The wording of the informed consent statement.**
- ✓ **The order of review.** Sometimes, all the committees independently review the proposal at the same time. At other times, the reviews are conducted "domino" style, with the proposal being independently reviewed and approved by one committee, then passed to the next committee, and so on.

24.6 Ongoing Review

All ongoing research protocols must be re-reviewed annually (or more often, at the discretion of the ethics review committee). All adverse events must immediately be reported to the IRB. Any desired changes to recruiting materials, the informed consent statement, the questionnaire, or other study documents must receive approval prior to being implemented. At the end of a study, most committees require a final report to be submitted that at minimum states the number of participants, affirms that no adverse events occurred, and declares that the project is concluded.

24.7 Conflicts of Interest

When a financial or other relationship (personal relationships, board membership, or others) could bias the design, conduct, or reporting of the study, the potential Conflict of Interest (COI) must be disclosed.

The disclosure of a potential COI is not an admission of bias, but it is an important assurance of transparency.

24.8 Is Ethics Review Required?

Institutional approval provides a degree of legal protection to the researcher, and many research sponsors will not release grant or contract funds until a research plan has been approved by a research ethics committee.

**** The decision to exempt a project from review can be made only by the relevant ethics committees.**

**** Research protocols cannot be retroactively approved, so researchers must take the time to undergo a formal review prior to collecting any data or analyzing any data files.**

32.1 Writing Checklists

(Outlining a Manuscript)

- ✓ **Established writing checklists can guide the content to include in reports.**
- ✓ **Outlining to the paragraph level before writing can help ensure that no critical information is inadvertently omitted.**
- ❖ The most common information included in each section: **>>>>>**

FIGURE 35-1 Key Content for Primary Research Manuscripts

Section	Content
Abstract (or Summary)	■ Summarize the article.
Introduction (or Background)	■ Provide essential background information. ■ State the objectives of the study (or, for experimental studies, the hypotheses tested).
Methods	■ Identify the study design. ■ Describe the person, place, and time characteristics of the study, explaining how the desired number of participants was estimated, how potential participants were selected and recruited, what the eligibility criteria were, and where and when data were collected. ■ Explain how data were collected and how potential sources of bias were minimized. ■ Describe the statistical or other methods used for analysis (including providing definitions for key variables in quantitative studies). ■ Discuss ethical considerations (such as which research ethics committee approved the project, whether an inducement was offered, and how informed consent was documented).
Results	■ Describe the study population, including the sample size (using a flow diagram to show the number of individual participants at each stage of the study, if that will be helpful to readers). ■ Report relevant results (using tables and figures when possible).
Discussion	■ Summarize (briefly) the key findings and state how they achieved the goals of the study. ■ Discuss the limitations of the study. ■ Describe the key implications of the study for practice, policy, and/or future research.
References	List all of the sources cited in the manuscript (and no sources that are not cited in the main text).
Title page or end matter	Provide the information requested by the target journal, such as a description of each coauthor's contributions, acknowledgments of the contributions of people who did not meet the authorship criteria, funding sources, and disclosure of possible conflicts of interest.

FIGURE 35-4 Common Reporting Guidelines

Study Approach	Checklist	
Case series	CARE	*Case Report*
	STARD	*Standards of Reporting of Diagnostic Accuracy*
	TRIPOD	*Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis*
Cross-sectional study	STROBE	*Strengthening the Reporting of Observational Studies in Epidemiology*
Case–control study		
Cohort study		
Experimental study	CONSORT	*Consolidated Standards Of Reporting Trials* (for randomized controlled trials)
	SPIRIT	*Standard Protocol Items: Recommendations for Intervention Trials*
	SQUIRE	*Standards for Quality Improvement Reporting Excellence*
	CHEERS	*Consolidated Health Economic Evaluation Reporting Standards*
	TREND	*Transparent Reporting of Evaluations with Nonrandomized Designs*
Qualitative study	SRQR	*Standards for Reporting Qualitative Research*
	COREQ	*Consolidated Criteria for Reporting Qualitative Research*
Tertiary study	PRISMA	*Preferred Reporting Items for Systematic Reviews and Meta-Analyses* (for evaluations of interventions)
	MOOSE	*Meta-analysis Of Observational Studies in Epidemiology*

Several checklists have been developed for the specific content that reports about particular types of research studies should present. For example, the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist can be used for primary and secondary reports about observational studies, such as cross-sectional, case–control, and cohort studies. The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist can be used for tertiary analyses of interventional **<<<<<** studies.

32.2 Abstract

The abstract is a paragraph-length summary of the article that serves a type of "advertisement" for the manuscript.

- **A structured abstract uses subheadings like objective, methods, results, and conclusion to highlight content.**
- **An unstructured abstract usually follows the same outline but doesn't list the section titles.**

**** Use synonyms;** If an abstract about hypertension includes only the word "hypertension," someone searching for "high blood pressure" might not find the article. A stronger abstract will include both "hypertension" and "high blood pressure." **Be careful about length!** Most journals limit abstracts to a maximum of 150 to 250 words.

32.3 Introduction

The introduction section (or background section) typically provides information about key definitions and foundational theories as well as overall goal and specific aims of the paper.

32.4 Methods

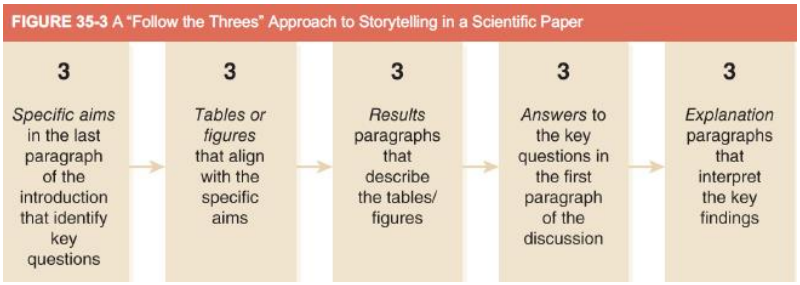
The method section typically describes the study design, the data collection, analysis methods, and ethical considerations.

** A well-written methods section exhibits coherence and transparency. **Coherence** is the quality of being logical and consistent. A coherent research report demonstrates the alignment of the study goals, the selected methodologies, and the featured results and conclusions. **Transparency** is the quality of being open and clear about the methods and results of a research study.

32.5 Results

The results section describes the study population and the key quantitative and/or qualitative results (without interpretation)**, using tables/figures when possible.**

One common organizational strategy for the results section is to match results paragraphs to the specific aims of the study. For example, if there are three specific aims, then the results section might have four paragraphs: one that describes the characteristics of the study population, one that presents the results most relevant to the first objective, one with results for the second objective, and one for the third objective. Another organizational approach is to write one paragraph about each table and figure.



32.6 Discussion

The discussion section usually begins with a brief summary of the key findings of the new study, then put them in context by comparing them to previous studies. The goal is not to show that the new study matches previous findings, but to show how the new study builds on previous research. A weak comparison section takes the form of "This study found X. Other studies also found X." A stronger comparison section uses prior publications to establish the context for the new study and explain the originality of the new results.

**** At least one paragraph typically describes the strengths and limitations of the study.**

**** The final paragraph usually presents conclusions and implications.**

32.7 End matter

- End Matter: is the information that some journals list between the end of the main text of an article and the start of the reference list

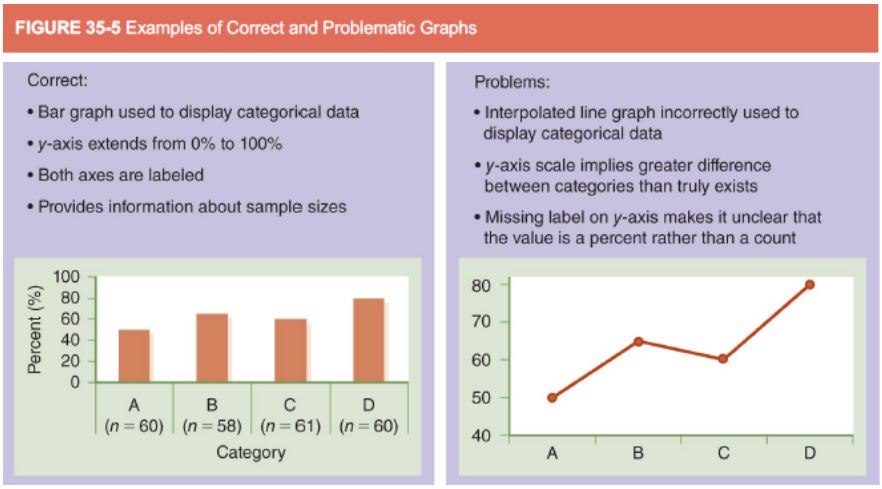
Some journals list author contributions, acknowledgments, disclosures of the presence or absence of possible conflicts of interest**, and other information** (e.g., a list of all funding sources) **after the main text.**

32.8 Tables and Figures

"A picture is worth a thousand words."

** A graph should provide enough information in the title, figure, and/or legend or key for a reader to be able to interpret the graph even without reading the related portion of the manuscript. **>>>>>**

** A high-quality table provides enough information that the contents can be interpreted and understood without reading the main text of the manuscript.



Chapter 33: Citing

33.1 Referring to the Scientific Literature

- **A typical article in the health sciences, refers to about 25 or 30 other articles published in peer-reviewed journals.**
- **Writers must read the full text of every article they cite; abstracts are not always accurate.**

** Authors should be cautious about citing commentary from the introductions and discussions of other papers, especially when the pertinent commentary is citing other sources. Suppose that "Paper 1" makes an interesting comment in its discussion section about the findings of "Paper 2" and "Paper 3." In that situation, the best option is to look up both "Paper 2" and "Paper 3" so that their methods and results can be examined and then cited if relevant. "Paper 1" does not need to be cited, because the supporting evidence for the new paper does not derive from the results of "Paper 1" itself.

A **retraction is the removal of a published article from the accepted scientific literature due to major errors or author misconduct. A retracted article has been withdrawn from the peer-reviewed scientific literature and should not be cited. A retraction is different from a correction. An **erratum** is a published correction to a minor error in an article that was introduced during the publishing process. A **corrigendum** is a published correction to a minor error in an article that was caused by the author rather than the publisher. If an erratum or corrigendum has been issued to correct an error in the article, the study's findings are still considered to be sound. The researcher should just be sure to read the updated version of the manuscript.

❖ Avoid citations of informal sources like factsheets.

Formal sources are scholarly works that were critically reviewed before being disseminated by a publishing group in a format that includes details such as author names, the name of the publisher, and the publication date. In the health sciences, peer-reviewed journal articles are typically the preferred source of evidentiary support. Books, book chapters, and scientific reports published by trusted governmental agencies and other organizations are also acceptable formal sources to cite.

FIGURE 33-1 Characteristics of Formal Scientific Reports

Formal Scientific Reports ...

- Are published in a peer-reviewed journal (or sometimes a peer-reviewed report or book), not on a website, in a newspaper, or in a popular magazine
- Describe the study design and explain why it was appropriate for the objectives of the study
- Explain how the study population was selected and demonstrate that the sample size was sufficiently large
- Explain how exposures and outcomes were defined and assessed
- Describe the analytic approaches used and present results using easily interpreted tables and graphs
- Draw conclusions that are reasonable and based on the study's data
- Discuss the limitations of the study
- Compare the new study to previous studies
- Follow a standard outline and other conventions for scientific writing

FIGURE 33-2 Citable Sources

Source	Formal or Informal?	Citable?	Remarks
Website or fact sheet	Informal	Rarely	Websites and fact sheets may be helpful starting places for informal research but should only be cited in a formal manuscript if they are from a trusted organization and no formal article or report provides the same information.
Newspaper or popular magazine	Formal/ Informal	Rarely	Popular media items should be referred to only when no formal scientific article or report provides the same information.
Statistical database	Formal/ Informal	Sometimes	Cite statistical databases and reports only when information is provided about how, when, and where the data were collected.
Official report	Formal	Yes	Reports are usually cited only when they are formal publications (with assigned publication years and/ or other bibliographic information) from trusted organizations.
Book or book chapter	Formal	Yes	Although most scientific communication occurs through journals rather than books, scientific books are acceptable sources for formal manuscripts; general textbooks are rarely appropriate sources, but some highly technical textbooks are appropriate to cite.
Abstract	Formal	No	Cite only full-text articles (and be sure to read the full text before citing them).
Article	Formal	Yes	Articles from peer-reviewed journals are the preferred references for formal manuscripts.

Informal sources like webpages, fact sheets, blogs, podcasts, and other types of information that are not peer reviewed and formally published should almost never be cited in formal research reports.

** The content posted on Wikipedia might be updated or deleted at any moment.

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33.2 Writing in One's Own Word

Almost no scientific articles quote directly from another source word for word. Paraphrasing (نقل بتصرّف) does not remove requirement to cite the original source; it just means that quotation marks do not have to be used.

FIGURE 33-3 Examples of Quoting and Paraphrasing

Quotation (almost never used in journal articles)	Paraphrase (often used)	Reference (always required for either a quotation or a paraphrase)
A case-control study examining risk factors for ovarian cancer in Canadian women found that "age at first full-term pregnancy was not associated with risk of ovarian cancer."[1]	A case-control study of Canadian women found no association between ovarian cancer and the ages of participants at the time of their first full-term pregnancies.[1]	1. Risch HA, Marrett LD, Jain M, Howe GR. Differences in risk factors for epithelial ovarian cancer by histologic type: results of a case-control study. *Am J Epidemiol* 1996; 144:363–72.

33.3 Common Knowledge and Specific Knowledge

- **<u>Specific knowledge</u>, such as a statistic or the result of a particular field or laboratory study, must be cited.**
- **<u>Common knowledge</u> (also called general knowledge) refers to what a typical person in the discipline knows, and it does not require a citation.**

When in doubt, err on the side of using a citation.

** أن تخطئ في الاقتباس بلا داعٍ أفضل من أن تخطئ في عدم اقتباس معلومة يجب اقتباسها!

33.4 Avoiding Plagiarism

Plagiarism (السرقة الفكرية) occurs when someone's wording, thinking, image, or creative output is repeated in a new document without attribution.

** <u>Thesaurus plagiarism</u> that swaps in synonyms for words in an original source in order to avoid the need for quotation marks is a form of plagiarism.

**** Plagiarism is a major violation of scholarly integrity, and it can have a damaging long-term impact on a professional career.**

**** Never cut and paste information from anywhere; "unintentional plagiarism" is still plagiarism.**

33.5 Citation Styles

Most of the citation styles used in the health sciences require two types of notations about each source of information:

- ✓ **In-text citations where the sources of information are briefly identified in the text.**
- ✓ **A reference list at the end of the document that provides full bibliographic information for each source.**

➢ **Common styles: APA** (recommended by the **A**merican **P**sychological **A**ssociation, and it is widely used by social science and nursing journals)**, and AMA** (recommended by the **A**merican **M**edical **A**ssociation, and it is widely used by medical and health science journals)**.**

Be careful to use a consistent style across all entries in the reference list.

(Restrict to one style)

FIGURE 36-4 In-Text Citation Styles

Citation Style	One Source	Two Sources	Three Sources
First author's last name and publication year	. . . [Ruiz, 2014].	. . . [Ruiz, 2014; Yamamoto, 2001].	. . . [Ivanov, 2008; Ruiz, 2014; Yamamoto, 2001].
Author(s) and publication year	. . . (Ruiz, 2014).	. . . (Ruiz & Sanchez, 2014; Yamamoto et al., 2001).	. . . (Ivanov, 2008; Ruiz & Sanchez, 2014; Yamamoto et al., 2001).
Number in brackets (square brackets)	. . . [1].	. . . [1, 2].	. . . [1–3].
	. . . .[1]	. . . .[1, 2]	. . . .[1–3]
Number in parentheses (round brackets)	. . . (1).	. . . (1,2).	. . . (1–3).
	. . . .(1)	. . . .(1,2)	. . . .(1–3)
Superscript number	. . . .[1]	. . . .[1,2]	. . . .[1-3]

- The reference list at the end of the article presents cited works either alphabetically in order of the first authors' last names or in the order of first appearance of the cited work in the text of the article. Sources appear only one time in each reference list. In AMA style, the first article cited is referred to as reference 1, typically denoted by a superscript 1, any time it is cited in the manuscript. In APA style, the authors' names are listed in the in-text citation every time the article is cited. The only change that occurs when an article is cited more than one time is that an article with three, four, or five authors will list all of the authors in the first in-text citation, but subsequent in-text citations will list only the first author's last name followed by "et al." (the abbreviation for the Latin phrase et alia, which means "and others"). If the article has more than five authors, all citations, even the first, include only the first author's last name and "et al."
- When preparing a manuscript for submission to a journal, authors should check the document carefully for compliance with the journal's style specifications. Journals using AMA style or a variant typically list authors by last name and first initials (with no periods after them), then the title (with capital letters only for proper nouns), an abbreviated journal name (which uses a formal journal title abbreviation, as specified in Index Medicus), the publication year, the volume number, and page numbers.

** A **digital object identifier (DOI)** is an alphanumeric code assigned to a document by a registration body to allow quick online access to the document or its abstract. Some publishers ask authors to provide it for all sources that have DOIs.

تم بحمد الله

كانت غزوة الخندق من أصعب الغزوات على المسلمين.. تحالف عليهم أقربُ الناس إليهم من عشائرهم مع أخبث الناس من العرب وأكثرهم حقدًا من اليهود.. وحاصروهم لأيام طوال..

كانوا قليلي العددِ والعُدة.. مروا بأقسى الليالي برودةً وأشدّها ظلمةً.. ربطوا على بطونهم حجارةً من شدة الجوع.. وكأن كل هذه المصائب لم تكفهم بعد.. فقام يهود بني قريظة بطعنهم في ظهورهم بنقضهم العهدَ معهم والتآمرِ ضدهم.. أحداثٌ مرعبةٌ زاغت لها الأبصارُ وبلغت بها القلوبُ الحناجرا

كانت كل المؤشرات تؤشر على هلاكهم.. وكل الأوضاع تراهن على إبادتهم.. لكن كان لحبيبنا وقائدنا مُحمدٍ رأيٌ آخر.. بشر المسلمين وقتها بفتح الشام واليمن وفارس!! تلك البلدان التي كانت تخضع لسيطرة أعتى الإمبراطوريات وأعظمها.. الروم والفرس !! وفعلًا هذا ما كان.. فقد كان - صلى الله عليه وسلم - وصحابته الكرام يظنون بربهم خيرًا.. فأنزل الله سكينَته على قلوبهم وأيدهم بجنود لم يروها.. أيدهم بملائكة تزلزل عروشَ المشركين وتحطم غرورَهم.. أرسل عليهم ريحًا وعواصفَ شديدةً اقتلعت خيامَهم وأسلحتَهم.. فعادوا خائبين.. وكان النصرُ حليفَ المؤمنين.

فيا زميل.. نجاحك في هذه الدنيا.. صلاتك في المسجد الأقصى.. وأولى لحظاتك في جنة المأوى.. أحلامٌ سترى النور قريبًا.. مهما مررت بظروف.. ومهما حملت من هموم.. اعقلها وتوكل.. واسْعَ حتمًا ستصل!

ملاحظة: الخطاب السابق موجه لكم ذكورًا وإناثًا.. فالمذكر في اللغة العربية يعم.. والمؤنث فيها يخص ..نعم.. نحن نفهم لغتنا العظيمة جيدًا.. "مش زي هظاك المجلس.."!!

رسالتنا الأخيرة لكم.. وفي آخر عطلة رسمية لكم - سامحكم الله على هكذا تخصص وأعانكم - هي الحفاظ على هويتكم العربية النقية.. ومبادئكم الإسلامية الزكية.. فأنتم نخبة أوطاننا شئتم أو أبيتم.. ستؤتمنون على صحة شعوبنا أطباءً.. وعلى تربيتهم وتعليمهم أمهاتٍ وآباءً ..ألا إنكم للأمة كالرماة على جبل أحد.. فإما أن تكونوا حصنًا لها.. وإما أن تُؤتى من قِبلكم. ذخرًا لها.. دمتم! https://youtu.be/VO7sGPHQ4sE