Integrative Practitioner

Clinical Research Guide

for Integrative Healthcare Professionals

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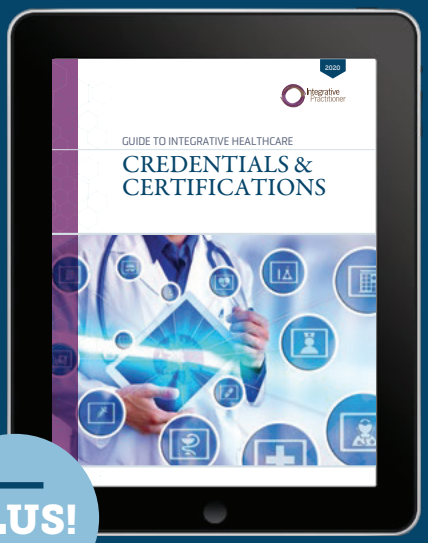

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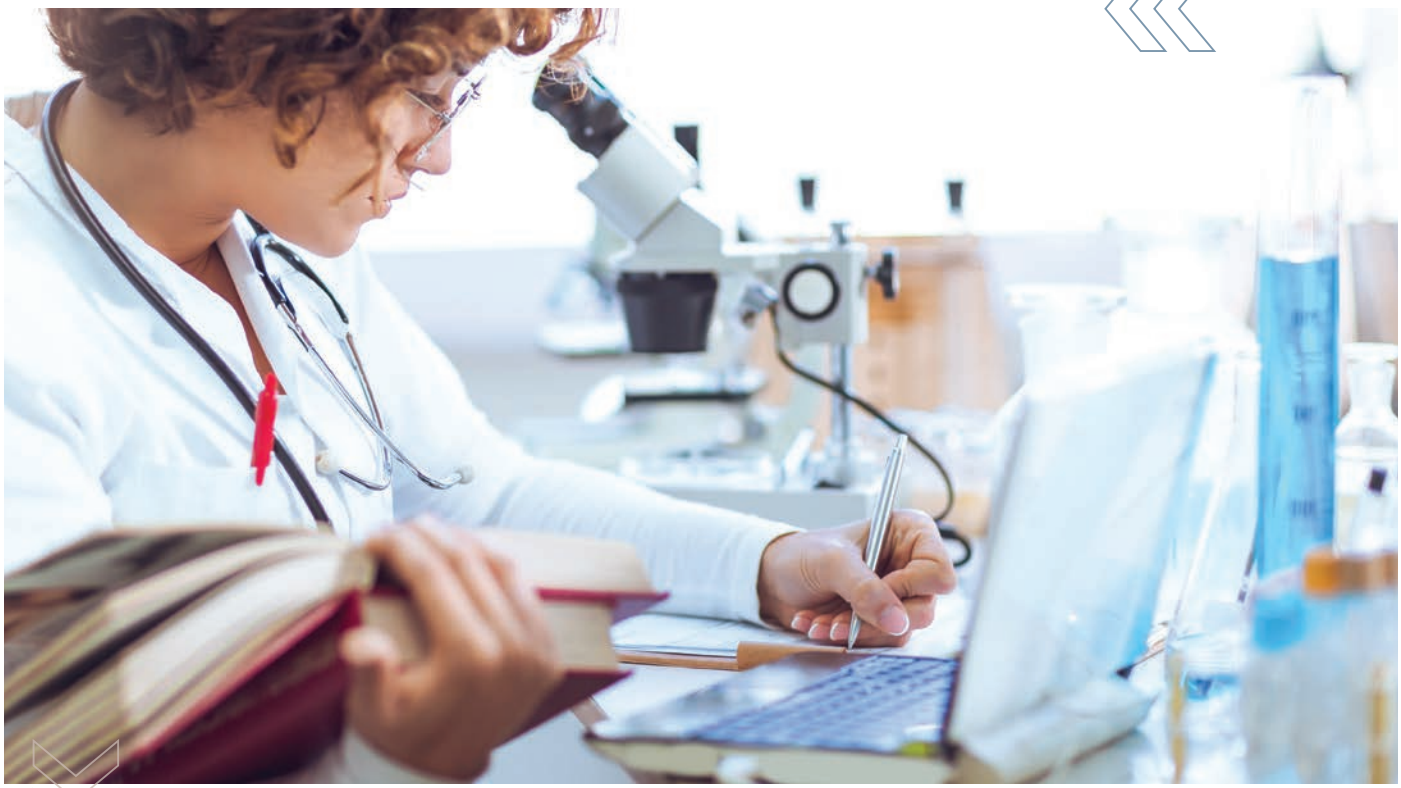
Challenges in Clinical Research



Scientific research can be complex, confusing, and occasionally contradictory. With a seemingly constant cycle of new studies and publications, identifying reputable sources and clinically useful information can be overwhelming for even the savviest healthcare professionals.

Beyond the volume of new information, in recent years, the research landscape has become increasingly politically and financially motivated. The scientific process is cluttered with conflicts of interest, and a researcher's success may not be measured by the quality of their questions or the rigor of their methods, but rather the number of studies they publish and how they can spin their research to appeal to the public.

The inherent conflicts surrounding most clinical research comes back to funding. In the United States, academic research is primarily funded through grants, mainly distributed by the federal government. Such grants are typically short-term and hard to come by. The National Institutes of Health, a major funding source for research in the U.S., approves less than 20 percent of the grant applications it receives. The lack of funding has led many scientists to avoid proposing in-depth and long-term projects necessary for truly groundbreaking research, instead opting for safer papers that take less time and are more likely to receive funding.

When independent, government, or university funding sources deplete, scientists may feel compelled to turn to industry or private interest groups that are looking to generate studies to support their possibly biased agendas. Nutrition science, for example, is primarily funded by the food industry, and many supplement trials by manufacturing companies.

The scientific culture experienced today in healthcare and beyond rewards safe results that garner flashy headlines, but all too often present inaccurate or misleading information. Scientific literature as it stands requires an objective lens to decipher what a study may prove and whether any findings extrapolated are clinically significant.

This Clinical Research Guide is intended to highlight the ideal scientific process and study design as a baseline standard for evaluating clinical research. We will review how to analyze data and statistics with a critical eye and offer pointers to effectively read research articles. Lastly, we will walk through common types of research-related questions that may come up in patient interactions.

In today's digital world, patients are more connected than ever to healthcare trends and advances and may come to you with questions about new and emerging research. Therefore, it is incumbent upon healthcare practitioners to effectively analyze scientific research and extract the appropriate information for the patient. •

Clinical Study Design

The scientific process, known formerly as the scientific method, in its purest form consists of systematic observation, measurement, and experiment as well as the formulation, testing, and modification of conjectures or hypotheses.

This ongoing process consists of several steps:

1. **Make observations**
2. **Formulate hypothesis**
3. **Experiment and collect data**
4. **Analyze results**
5. **Accept or reject hypothesis**
6. **Repeat until hypothesis is achieved**

This process of hypothesis testing, at its core, involves narrowing down what is most likely true by showing what is not true. The quality of evidence depends on several factors, mainly how the study is designed and executed.

Conventionally, research is classified as either quantitative or qualitative. Quantitative research deals with numbers and statistics, while qualitative research deals with words and meanings. Quantitative methods allow scientists to test a hypothesis by systematically collecting and analyzing data, while qualitative methods allow scientists to explore ideas and experiences in depth.

There are six types of qualitative research: the phenomenological model, the ethnographic model, grounded theory, case study, historical model, and the narrative model. Additionally, there are four types of quantitative research design: descriptive research, correlational research, causal-comparative/quasi-experimental research, and experimental research.

In healthcare, the most common study designs for clinical trials are non-experimental and experimental. Non-experimental studies, also known as observational studies, are studies where researchers observe or measure the effect of a risk factor, diagnostic test, treatment, or other intervention. No attempt is made to affect the outcome. Types of observational studies include cohort studies, case-control studies, and cross-sectional studies.

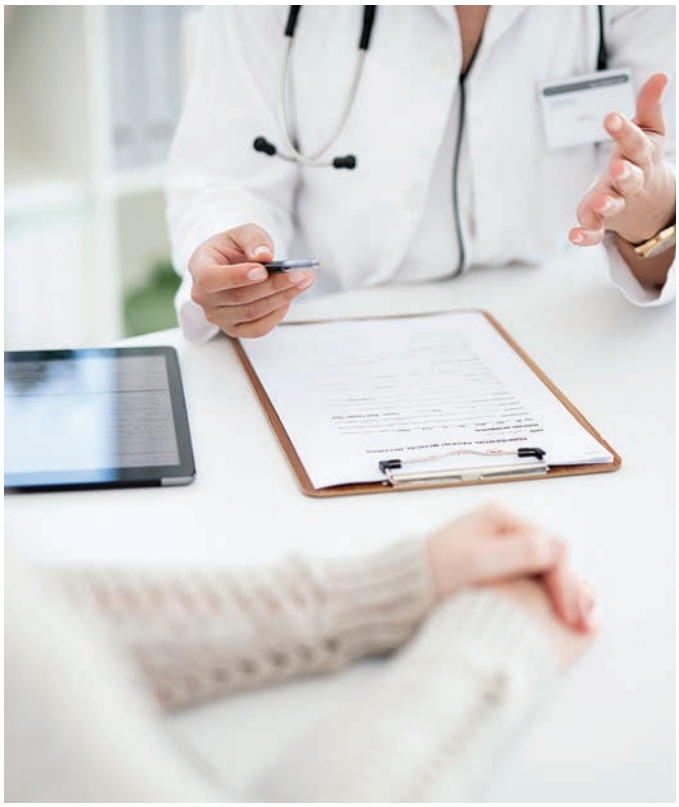
Experimental studies include those where researchers introduce an intervention and study the effects. Experimental studies are usually randomized, meaning the subjects are grouped by chance. Randomized controlled trials are considered the gold standard in clinical trial design.

For the purposes of this guide, we will be focusing different types of clinical medical studies, including case reports, correlational studies, cross-sectional studies, case-control studies, cohort studies, randomized controlled trials, practice guidelines, systematics reviews, and meta-analyses.

Case Reports

A case report or case series is an article that describes and interprets an individual case or small group of cases. Case reports are often written in narrative form and may include novel cases that cannot be explained by current clinical understanding and variations of known diseases or conditions.

Case reports may lead to the formulation of a new hypothesis concerning possible risk factors for a disease, which are often relevant to clinical practice. However, these reports reflect the experience of only one patient or a small group of patients and often lack an appropriate comparison group.



Correlational Studies

A correlational study is a statistical analysis that observes two or more variables to see if there is a relationship between them. This relationship may be positive or negative.

Correlational research can be done quickly and is often inexpensive. It typically uses existing data and considers large populations. However, these types of analyses cannot control for the effects of potential confounding variables (other factors that may cause a correlation.) Additionally, correlation does not equal causation. Correlational studies do not demonstrate cause and effect.

Cross-Sectional Studies

A cross-sectional study or survey analyzes data from many different individuals at a single point in time. These studies help assess exposure and disease risk at the same time, while providing information on the prevalence of disease or outcomes in certain groups of individuals.

Cross-sectional studies could be used to determine if exposure to certain risk factors might correlate with particular outcomes. For example, past smoking habits and current lung disease diagnosis. Results are limited in that they cannot determine if exposure preceded or resulted from the disease or outcome.

Case-Control Study

A case-control study compares cases with controls, or patients who have a disease or outcome of interest with patients who do not have the disease or outcome. These studies look retrospectively to compare how frequently exposure to a risk factor is present in each group to determine possible relationships between the risk factor and the disease or outcome.

Case-control studies are sometimes referred to as retrospective studies or case-referent studies. They are relatively quick and inexpensive to conduct and allow the researcher to examine multiple etiologic factors for a single disease. This type of study is optimal for the assessment of rage diseases and evaluation of diseases with long latent periods.

The downside of case-control studies is that they are prone to selection and recall bias. Selection bias occurs when a sample of people is not representative of the larger population that researchers are looking to make inferences about. Recall bias is the inability to accurately remember past behaviors, as often seen with self-reported data. Additionally, unless the study is population-based, it is not able to directly compute incidence rates of disease.

Cohort Study

A cohort study is a type of longitudinal study used to investigate the causes of disease and establish links between risk factors and health outcomes. These types of studies look at groups of people, or cohorts, and can be either prospective or retrospective. Prospective studies are planned in advance and carried out over a period of time. Retrospective studies look at data that already exist and try to identify risk factors for particular conditions. Interpretations in retrospective studies are limited because researchers cannot go back and gather missing data.

Cohort studies typically observe large groups of people, recording their exposure to certain risk factors to find clues as to the possible causes of disease. These types of studies can also be helpful in identifying potential social factors that influence health. An example of a cohort study would be looking at whether exposure to smoking associates with lung cancer.

Adherence

Adherence can be a challenge in randomized controlled trials. Non-compliance can drastically alter trial results, so pay attention to how the researchers ensured optimal adherence to the trial assignment.

Efficacy, Effectiveness, and Efficiency

When reviewing clinical research, *efficacy*, *effectiveness*, and *efficiency* are terms frequently used. *Efficacy* evaluates how well a test, medication, or procedure works, and is determined with randomized controlled clinical trials. *Effectiveness* assesses how well a test, medication, or procedure works under usual circumstances, or to what extent the intervention does what it is intended to do when applied to the general population. *Efficiency* evaluates the costs and benefits of an intervention.

Randomized Controlled Trials

A randomized controlled trial is a type of experiment that randomly assigns participants into experimental groups or control groups. The aim of randomized controlled trials is to reduce sources of bias when testing the effectiveness of new treatments. This is accomplished by randomly allocating subjects to two or more groups, treating them differently, and then comparing them to a measured response.

Clinical trials provide the strongest and most direct epidemiologic evidence about the existence of cause-and-effect relationships, if properly executed. Randomization minimizes potential bias and confounding. However, these kinds of experiments are expensive and time-consuming, and it may not be feasible to find a sufficient representative population for the study. In many cases, there is also a high degree of control that limits external real-world validity.

Practice Guidelines

A practice guideline, also known as an evidence-based guideline or clinical guideline, is a statement produced by a panel of experts that outlines current best practices to inform healthcare professionals in making clinical decisions. These statements require extensive review of literature and are often created by professional associations, government agencies, and other public or private organizations.

An ideal practice guideline clearly defines the topic, summarizes high quality evidence, and identifies decision points as well as how the information integrates into clinical practice. Practice guidelines are typically reviewed extensively and updated as needed.

Bias is possible, as recommendations might be influenced by the organization creating the practice guideline. They can also take considerable time to produce and are slow to change and update.

Systematic Reviews

A systematic review is a comprehensive review of all relevant studies on a specific clinical topic or health-related question. It requires an exhaustive review of all information from both published and unpublished studies and a summary of the findings. These reviews are less costly than creating a new study and results can be applied to the general population, resulting in improved external validity.

These evidence-based resources are very time-consuming and combining studies can be challenging. However, they are considered more reliable and accurate than individual studies.

Meta-Analyses

Meta-analyses systematically combine data from several studies to derive conclusions about a body of research. They are considered statistically stronger than individual studies because they often include more subjects, greater diversity of subjects, and accumulated effects and results. While it is not required, meta-analyses that include only randomized controlled trials are considered the highest level of evidence on a clinical topic.

A meta-analysis offers greater statistical power, but they are challenging and time-consuming to prepare. Not all studies include adequate data for inclusion, and conducting a meta-analysis requires complex statistical techniques.

Advantages of Disadvantages of Various Study Designs

There is no such thing as a perfect study design. As research is conducted by humans, there are always inherent biases and potential for errors. There are strengths and limitations throughout the hierarchy of evidence. Practitioners should understand these potential pitfalls to better identify and extrapolate quality information.

Independent and Dependent Variables

The independent variable is the variable the researcher changes or controls and is assumed to have a direct effect on the dependent variable. The dependent variable is the variable being tested and measured in an experiment and is dependent on the independent variable.

Non-Experimental Studies

Non-experimental, or observational studies, include large populations over long periods of time. They examine potential associations that occur over longer periods and allow for the generation of hypotheses that can be further studied in randomized controlled trials.

Non-experimental studies cannot establish cause-and-effect. They also lack the control of variables, which increases the chance of false associations.

Experimental Studies

Experimental, or interventional studies, allow for the demonstration of cause and effect. Researchers can control many variables and explore mechanistic explanations for the observed effects.

The high degree of control seen in many experimental studies, however, is not easily replicated in the real world, which leads to limited external validity. Additionally, these studies can only examine a limited number of subjects at a time and are often shorter duration.

Elements of a Clinical Trial

The central elements of a clinical trial include a research question, hypotheses, study design, participants, recruitment, allocation, masking or blinding, treatment groups, data, analyses, and interpretation of results.

The research question is critical in the design of a clinical trial. The question may aim to assess the efficacy or the effectiveness of an intervention. The research question informs the development of hypotheses, which prompts the appropriate study design.

There are many forms of hypotheses, including simple, complex, and null, as well as empirical, alternative, logical, and statistical. A simple hypothesis is a prediction of the relationship between two variables, known as the independent variable and the dependent

Confounding

A confounding variable, or confounder, is an extraneous variable that influences both the dependent and independent variables. It can impact the association between the variables.

Interpret Negative Results

Negative results in clinical trials occur for one of two reasons: the treatment is worthless, or the treatment is worthwhile, but the study has bias against the treatment, inadequate contrast between groups, or insufficient statistical power. Further study or a meta-analysis are potential remedies.

variable. A complex hypothesis examines the relationship between two or more independent variables and two or more dependent variables. A null hypothesis exists when a researcher believes there is no relationship between the two variables, or there is a lack of information, so the aim is to disprove or discredit.

Study participants are key to the success of a clinical trial. From a target population, researchers typically identify an accessible population, from which they select the study sample. The accessible population is typically at high risk for the disease or a candidate for the treatment being studied. It should be representative of the target population. Additionally, the investigators must specify inclusion and exclusion criteria for participation in the study.

Treatment allocation in a clinical trial can be randomized or nonrandomized. Randomization is best practice, as it eliminates bias and reduces confounding from known and unknown confounders.

Masking or blinding can also help avoid bias and potential error. Clinical trials may be single blind, double blind, or triple blind. In a single-blind trial, the observers or individuals who collect the outcome variable do not know the treatment assignment. In a double-blind trial, study participants and observers do not know treatment assignments. In a triple-blind trial, data interpreters, study participants, and observers do not know treatment assignments.

Trial participants are divided into groups, mainly an active treatment group and a comparison group. The comparison group may receive a placebo, usual care, or a provision of standard therapy known as active control. Usual care and active control are most common. However, the standard of care approach can be problematic in that variations are common.

Once baseline data has been collected, researchers determine eligibility, describe study participants, define subgroups, and address confounding, as well as measures of adherence and outcome variables. Outcome variables include both principal outcomes and secondary outcomes. The principal outcome is the most important variable after randomization, specified in the hypothesis, and determinant of the sample size. Secondary outcomes are relevant to the research question.

Outcome variables should be clinically relevant and easy to measure. They should offer little measurement error. Random errors lead to imprecision and systematic errors lead to bias. Ideal outcome variables are also masked or blinded.

Surrogate outcomes are a laboratory measurement or physical sign used as a substitute for a clinically meaningful outcome. Surrogate outcomes typically increase statistical power compared to clinical outcomes. Surrogate outcomes are often continuous and measured repeatedly, whereas clinical outcomes are categorical and measured until an outcome occurs. Further, surrogate outcomes allow for shorter follow-up periods, reduced sample sizes, and lower costs, and are particularly useful in studies of mechanisms. However, measurement of surrogate outcomes can involve complex, technical procedures and missing values and bias are common.

Analytic techniques for clinical trials include crude analyses and adjusted or regression analyses. Analysis depends on the type of outcome data. Basic tests include continuous outcome variable and dichotomous or categorical data. Regression determines association between exposure and outcome.

The interpretation of results includes both internal and external validity. With internal validity, conclusions correctly describe what happened in the study. External validity, or generalizability, describes the degree to which the conclusions apply to the study population and other populations.

A quality study will include thoughtful discussion and conclusion, with clear key points. The interpretations are appropriate, and conclusions are accurate, not misleading. Additionally, researchers should include limitations of the study, consideration of alternate explanations or interpretations, both statistical and meaningful differences, practical significance, and recommendation for future study. •

Understanding Data and Statistics

Statistics is the study of numerical information known as data. Quality data is the backbone of scientific research and good data allows for the development of good conclusions.

Data and statistics are incredibly complex and top-level statisticians commit to years of study to master these subjects. There are several core concepts that make statistics and data easier to comprehend and are critical when analyzing clinical research or a study's effectiveness. This section will offer an introductory glance and some central themes in statistics to help practitioners better understand how data is gathered and presented.

Samples

Populations and samples are at the center of statistics and data. A population is the entire group a researcher wants to draw conclusions about. A sample is the specific group the researcher will collect data from. The sample size is usually randomly selected and always smaller than the total population size.

There are several sampling techniques that ensure the sample is as representative as possible of the total population. There are five types of sampling, including random, systematic, convenience, cluster, and stratified.

A random sample is a sample that is chosen randomly. Random samples are used to avoid bias and other unwanted effects. A simple random sample is one random sampling technique and is a subset of individuals chosen from a larger population.

Systematic sample involves the selection of elements from an ordered sampling frame.

There are several statistical tests that can be performed on data, which are important when reviewing clinical research.

Convenience sampling involves the sample being drawn from that part of the population that is close to hand. In cluster sampling, the total population is divided into groups and a simple random sample of the groups is selected. Lastly, stratified sampling draws involves dividing a population into subgroups, followed by random samples taken in the same proportion to the population from each of the groups or strata.

Practitioners should always scrutinize the way a population is sampled. The sample size and quality can drastically influence study results.

Data Collection

Additionally, when reading a study, it's important to understand how the data was collected. The most common methods include:

- **Observation**
- **Questionnaire**
- **Interview**
- **Focus group discussion**

There are advantages and drawbacks to each, but generally self-reported data is weaker and more error-prone than data collected or measured directly by the researcher.

Statistical Tests

There are several statistical tests that can be performed on data, which are important when reviewing clinical research. For the purposes of this guide, we will focus on measures of central tendency and dispersion, and how they help in understanding a given dataset.

Measures of Central Tendency

The three most common measures of central tendency are the mean, median, and mode. The mean, also known as the average, is found by adding all numbers in the data set and then dividing by the number of values in the data set. Considered the basis for statistical tests, the mean is preferable for statistical analysis and tests of significance. However, it is easily influenced by outliers.

The median is the middle value when a data set is ordered from least to greatest. It is unaffected by outliers and may be a more informative measure than the mean if the distribution of the dataset is skewed. The median is less amenable than the mean to tests of statistical significance.

Lastly, the mode is the number that occurs most often in a data set. It can provide insights

into possible etiology of disease but is even less amenable to tests of statistical significance than the median. Additionally, positively skewed distributions can be misinterpreted as bimodal.

Measures of Dispersion

Measures of dispersion, or variability, provide information regarding the relative position of other data points in the sample. These measures include the range, variance, standard deviation, coefficient of variation, and standard error of mean.

The range of a data set is the difference between the largest and smallest values. It is

Statistical analysis helps distinguish true differences and associations from chance results.

simple to calculate and easy to understand, but not a stable estimate as it can increase as sample size increases. It is also sensitive to outliers.

Variance is a measurement of the spread between all numbers in a data set. It provides a summary of individual observations around the mean but is also sensitive to outliers.

Standard deviation is a measure of the amount of variation or dispersion of values in a data set. A low standard deviation indicates that the values tend to be close to the mean of the set, while a high standard deviation indicates values are spread out over a wider range.

The coefficient of variation, also known as relative standard deviation, measures the dispersion of data points in a data series around the mean.

Lastly, the standard error of mean measures the accuracy of a sample mean by identifying how far the sample mean likely is from the true population mean. It is used to compare means of different populations.

Statistical Versus Clinical Significance

Studies can be statistically significant without a clinically significant outcome. When a difference in an outcome between exposures is observed, practitioners should consider whether the effect is due to the exposure or if an alternate explanation exists.

Statistical significance pertains to whether the observed results could occur from chance alone. Clinical significance pertains to whether the observed results have clinical relevance. Typically, if an observed difference is deemed clinically insignificant, it is most likely statistically insignificant. However, if an observed difference is clinically significant, it may be important or warrant further investigation even without statistical significance.

Statistical analysis helps distinguish true differences and associations from chance results. When reviewing a clinical study, consider the sample size, variability, and effect size. Larger sample sizes reduce potential for random error and variation, as well as increase the ability to identify statistically significant differences between groups. Significance is also influenced by the effect size, or the magnitude of the observed effect between treatment groups.

Good quality research also includes consideration of the standard error. This allows the researcher to determine the probability of having obtained the result by chance. This is expressed as the p-value, which is evidence against the null hypothesis.

Statistical significance alone is not enough to establish a causal relationship between exposure and outcome. Clinical significance comes down to the effect size. If the effect size is big enough, it may warrant considerations for change in clinical care. ●

Roadmap for Reading Research Articles

Practitioners may feel overwhelmed when reading published studies, especially when the goal is to identify potential relevance to clinical practice. When reading a clinical study, it is important to understand the goal or goals of the research. Some guiding questions to ask when reviewing may include:

- **What is the research question?**
- **What is the study goal(s)?**
- **What is the study design and is it appropriate for the question at hand?**
- **What statistical tests are used and how do they influence the results presented?**
- **Does the study answer the research question?**

Identifying the research question or hypothesis is essential when reviewing medical research. It is also important to understand the goal or goals of the study, which ultimately determine the best study design and statistical tests:

- **Is the goal to determine efficacy?**
- **Is the goal to determine effectiveness?**
- **Is the goal to determine causes or associations?**

Other considerations when reading clinical research include:

- **Sample size and representation**
- **Measures of significance and effect size**
- **Potential conflicts of interest and bias**

How to Spot Study Weaknesses

Poorly designed studies are a major concern in scientific research. This is because statistical flaws in published research are often undetected. In today's competitive research environment, researchers may feel pressured to hype up their results to get further funding or to get published. They may focus on a small data component or manipulate the study design to garner more favorable results. There is also an increased concern that some researchers only report studies that produce statistically significant results or alter the statistical analysis altogether.

There are many potential pitfalls for each type of study design, but the good news is such flaws are often identifiable with a cautious eye. Here are some considerations when reviewing various types of studies that may reveal study weaknesses:

- **Is the sample or subject(s) described in detail?**
- **Does the study include carefully recorded, unbiased observations?**
- **Is the control group appropriate for the population?**
- **Does it use appropriate inclusion and exclusion criteria?**
- **Are there any confounding variables?**
- **Does the study address and mitigate confounding variables?**
- **Is the randomization truly random, or are there two populations being studied?**
- **Do the study authors have any inherent biases or conflicts of interest?**
- **Is the study produced by independent scientists or by public or government agencies, professional associations, or private companies or institutions?**
- **Is the study funded by independent resources or by public or government agencies, professional associations, or private companies or institutions?**
- **Do the analyses fit the variables being studied?**
- **Does the study include alternative explanations or discuss negative outcomes?**

Funding Sources

Funding for scientific research is highly competitive and in limited supply. The funding source is incredibly important to identify as it can reveal inherent biases or conflicts of interest. While most peer-reviewed journals screen this for the reader, practitioners should review the funding source and the funding source's sponsors, leadership, and other stakeholders, particularly if a study seems too good to be true or makes egregious claims.

Be Skeptical

Practitioners should always remain critical of both the source of the research article and the journal its published in. Many special interest groups publish their own journals, which may not have the same standards as an independent, peer-reviewed publication.

In the United States, research is funded through academic, government, and private entities. The most common source of funding in the U.S. is grants, which can be found through free resources such as:

- **The National Institutes of Health (NIH)**
- **Grants.gov**
- **The National Science Foundation**
- **Newton's List**
- **Terra Viva Grants Directory**
- **The Spencer Foundation**

Paid subscription funding resources also exist for grant applications, including The Foundation Center, Pivot, and the Sponsored Programs Information Network. These services charge a fee to access their grant databases, which is not feasible for all researchers.

Evaluating Sources of Information

In research, a hierarchy of evidence exists, from non-peer-reviewed media with the highest potential for bias and error through systematic reviews and meta-analysis with the lowest potential for bias and error. Unfortunately, in today's constant news cycle where new research is published daily in a variety of mediums, it can be challenging to differentiate quality, reputable sources from flawed or biased sources.

In general, the highest quality sources are scientific journals that require submitted manuscripts go through a process called *peer review*. Peer review is the evaluation of work by one or more people with similar competencies as the author of the work. The purpose of peer review is to ensure that only high-quality research is published, especially in reputable scientific journals, by determining the validity, significance, and originality of the study. Additionally, peer review is intended to improve the quality of manuscripts that are deemed suitable for publication.

Peer Review Process

Study completed ▷ Submitted for publication ▷ Peer-reviewed by reviewer(s) ▷ Modifications made ▷ Study rejected or accepted ▷ If accepted, study published

Types of peer-reviewed journal articles include position papers or scientific consensus statements, systematic reviews and meta-analyses, individual studies, and narrative reviews.

There are also many high-quality, non-peer-reviewed sources. These include academic textbooks from reputable universities, public health websites, government health websites, conference presentations by primary researchers, and interviews with primary researchers. When evaluating a non-peer-reviewed source of information, it's important to consider factors like its funding resources, stakeholders, and anything that could indicate potential bias.

Lastly, there are many poor-quality sources that purport outlandish health claims or report on research with flashy, oversimplified headlines. These include popular media, anecdotes and testimonials, advertisements, and most blogs. Patients may utilize such resources and develop opinions or questions, so practitioners may consider identifying alterative primary research on related topics.

Primary and Secondary Research

Primary research is any type of research gathered through self-conducted methods. Secondary research is information gathered from previous studies. Both primary and secondary sources are useful in clinical research review.

When determining whether a source is good quality, consider the following questions:

- **Is the source published in a peer-reviewed journal?**
- **Is it a position paper or scientific consensus?**
- **Does it come from a government website or professional scientific organization?**
- **Is it a systematic review or meta-analysis?**
- **Is it a presentation or interview with primary researchers without a brand, agenda, or product to promote?**

If a source does not fall under one of these categories, it may not be a reliable source. Sources that require further scrutiny include:

- **Individual study**
- **Narrative review**
- **Popular media, advertisement, or blog**
- **Non-peer reviewed sources**
- **Other types of journal articles**
- **Other sources**

Individual studies provide valuable results but don't offer the weight of the scientific evidence for a topic. Narrative reviews can provide an overview of evidence but are subject to bias. Information from popular media, anecdotes and testimonials, advertisements, and blogs tend to be low quality. Non-peer reviewed sources that don't come from professional or government sources should be assumed as low quality. Other types of journal articles, like letters to the editor, are important for scientific discussion, but do not carry the same weight as reviews, studies, and analyses. Lastly, other sources that don't fit under a specific category may not be as reliable, so practitioners should use caution when reviewing.

Who's Who in Research Authorship

Most published scientific research has a lengthy list of authors and contributors. While it may seem minor, the sequence and status of each author must accurately reflect the extent of their involvement to avoid conflict of interest.

The lead author, also called the first author or principal investigator, is the one who carries out the research and writes and edits the manuscript. Corresponding or co-authors collaborate with the lead author and contribute to the work in the manuscript. A senior author typically serves in a supervisory capacity, though may take responsibility for writing the paper.

The sequence of authors in published studies may depend on the publication, but typically features the lead author first, the co-authors ordered based on their overall contributions, and the senior author last. In some instances, the senior author may put their own name before the lead author.

Conclusions are always tentative, and nothing is ever completely certain. Therefore, practitioners should avoid cherry-picking individual studies and instead look at the overall weight of the evidence. •

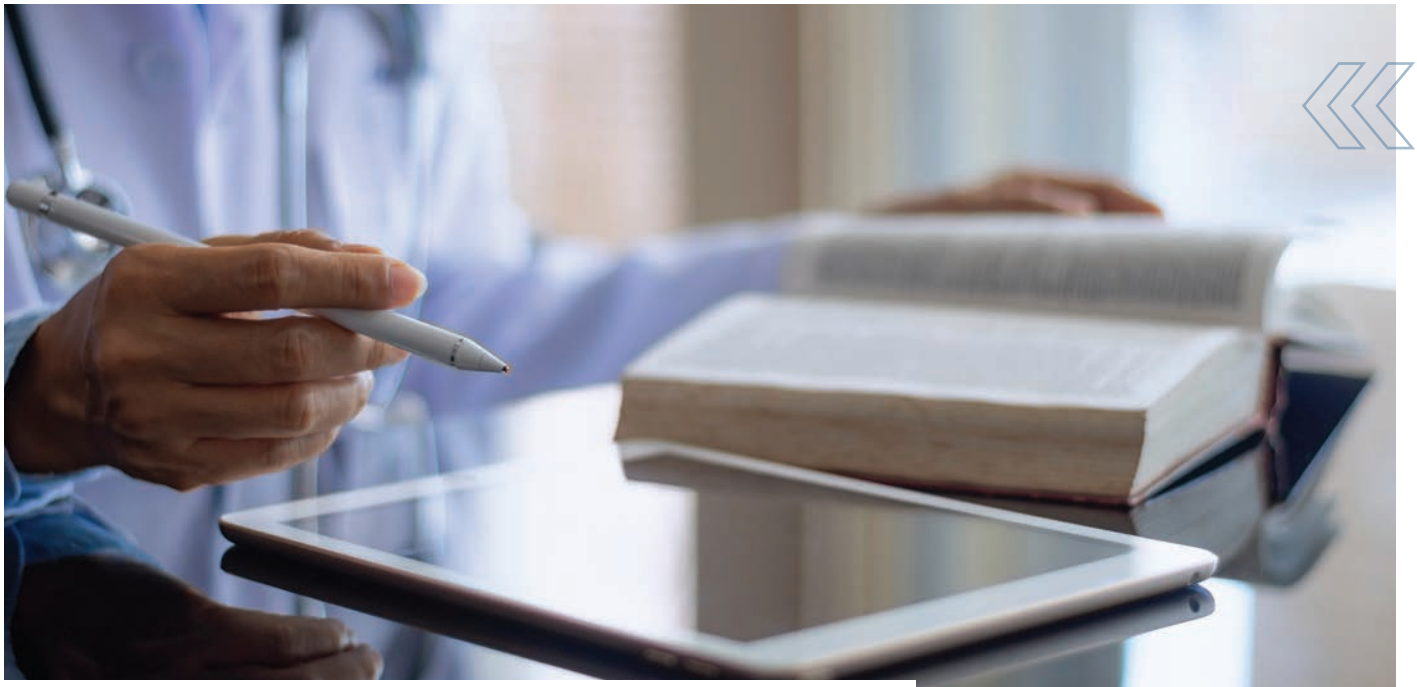
Approaching Patient Research Questions

With new and emerging research making headlines almost every day, patients are more aware of scientific advances than ever before and may go to their practitioner with questions. For example, let's say a news organization reports on a study that claims eggs lead to high cholesterol. A patient struggling with high cholesterol may read this and completely remove eggs from their diet. Now, let's say that same news organization reports on another study a few weeks later, only this time touts the benefits of egg consumption on cholesterol. The patient is left confused and decides to consult their physician about whether eggs are "good" or "bad."

While this example may be fictitious, the scenario is all too reminiscent of real studies on nutrition, supplements, diets, and other programs and procedures that patients may come across in the news or social media and take to heart. Thus far, this resource has focused on how to extrapolate clinically useful information from scientific research. This section will help you put that knowledge to practice and clear up confusion with patients.

Listen to the Patient

Patients who take the time to read health-related articles or research their symptoms and potential treatment options likely care



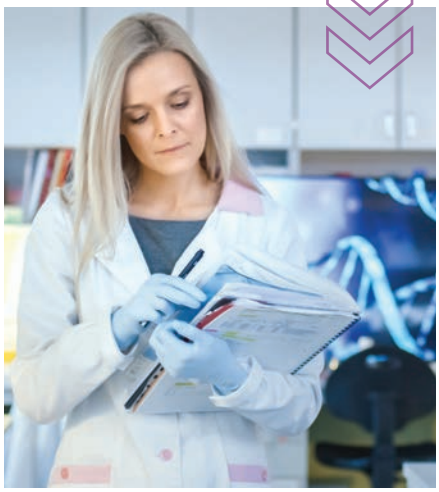
Consider Consumer Perspectives

Take the time to identify where your patients consume news and information. Familiarize yourself with headlines coming from magazines, television, and social media and be prepared to address trending topics.

about their wellbeing. However, even when a new study offers clinically relevant takeaways, it's often difficult for non-healthcare professionals to interpret correctly. The best option is to first listen to the patient's point of view. Find out more about the information they encountered and, if possible, look up the study or studies yourself. Take time to understand what the patient is curious or concerned about and give them credit for their commitment to their health. Then, offer your own perspective and recommendation. If possible, give the patient options to choose from and develop a working therapeutic relationship where their voice is both heard and directly considered.

Educate

Take the opportunity to provide some education about health, science, and clinical studies, so your patients have the tools to separate flashy headlines from real science. Explain concepts using details they already know and find ways to make it relevant to them. This may take some initial work to get to know your patients from a broader perspective but will ultimately ensure your patient is satisfied with the answers you've provided them.



Many people do not understand the connection between health-related messages and the research behind them. When talking about scientific research and clinical trials with patients, keep it simple. Find out what they know and go from there.

If the patient has questions about the process, start by describing what a research study or clinical trial is in plain language. Clarify your definition with an example that will make sense to the patient. If the patient is more concerned with the result, there's no need to offer a definition, and instead focus more generally on what the study found and how it might apply to the patient.

Offer Resources

Practitioners may consider creating a general resource or worksheet for patients that explains the basics of clinical research and how to identify quality information. An example is provided in this guide.

Another option is to highlight clinical research from popular media in regular patient communications. If your practice has a regular e-mail newsletter or blog, consider a short monthly round-up of trending studies, where you identify the headlines and offer your own expert takeaway, as well as what it means for your patients.

Education should be light-hearted and informative, not condescending. Encourage patients to come to you with questions about clinical studies, especially information that might be relevant to them. •

Checklist for Analyzing Scientific Research

This worksheet is intended to help identify a quality scientific paper and can be used as a quick reference when

Study Title:

- ☐ **What question(s) is this study is trying to answer?**
- ☐ **What is the goal of this study?**
- ☐ **What is the study design?**
- ☐ **What types of tools and tests are used to measure and analyze the data?**
- ☐ **How many participants are included in this study?**
- ☐ **What is the study conclusion?**
- ☐ **What are the potential biases or conflicts of interest of the authors, publication, etc.?**
- ☐ **What is the funding source of the study?**

Is the study design appropriate?	**Yes____ No____**
Does the study account for variability, confounding variables, etc.?	**Yes____ No____**
Is the study sample representative of the target population?	**Yes____ No____**
Does the study address potential biases (selection bias, recall bias, etc.)?	**Yes____ No____**
Is the data analysis reported correctly and appropriately?	**Yes____ No____**
Does the study include effect size or other measures of significance?	**Yes____ No____**
Are the results organized clearly and completely?	**Yes____ No____**
Is the conclusion clearly stated with key points?	**Yes____ No____**
Are the interpretations of the results appropriate?	**Yes____ No____**
Does the study include limitations, alternative interpretations, implications, and recommendations for future study?	**Yes____ No____**
Are the study authors, publication, funding sources, etc. free of bias or conflicts of interest?	**Yes____ No____**
Are the findings clinically significant?	**Yes____ No____**

Based on your answers to the above questions, brainstorm what information, if any, might be clinically relevant in your patient practice. If the results are not clinically significant, how might you address patient questions about this study if it is reported in the media?

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