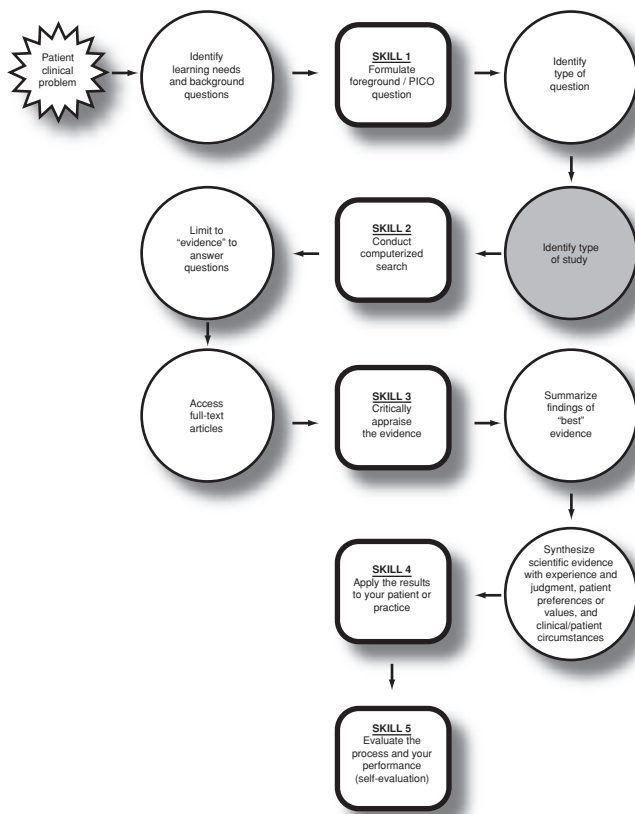


Research Design and Sources of Evidence

PURPOSE

The purpose of this section is to discuss sources of scientific evidence and characteristics of research designs that constitute the evidence. Although evidence-based decision making (EBDM) emphasizes using randomized clinical trials and other quantifiable methods, this focus has evolved to include qualitative research and acknowledging that different research designs contribute to a continuum of knowledge.



OBJECTIVES

After completing this chapter, readers will be able to:

1. Identify what constitutes evidence.
2. Explain the difference between research and evidence.
3. Identify sources of primary and secondary evidence.
4. Discuss the difference between experimental and non-experimental research.
5. Identify distinguishing characteristics of different research methods: randomized control, cohort, case control, case series, and case report studies.
6. Discuss the difference between quantitative and qualitative research and the role of qualitative research in EBDM.
7. Identify scientific sources of evidence to use in clinical decision making.

SUGGESTED ACTIVITIES

Quiz
Critical Thinking Questions
Exercise 3-1

SOURCES OF EVIDENCE

Scientific evidence is the product of well-designed and well-controlled research investigations that minimize sources of bias. Evidence is considered the synthesis of all valid research studies that answer a specific question. As such, a single research study does not constitute “the evidence,” but rather contributes to a body of knowledge that has been derived from multiple studies investigating the same phenomena.¹ Thus, the body of evidence evolves over time as more research is conducted, underscoring the importance of staying current with the scientific literature. Once synthesized, evidence can help inform decisions about whether a method of diagnosis or a treatment is effective relative to other diagnostic methods or treatment and under what circumstances. The challenge in using EBDM arises when there is only *one* research study available on a particular topic. In these cases, individuals should be cautious in relying on the study because later it can be contradicted by another study or have used poor methods or it may only test efficacy (safety and how well an intervention performs under ideal conditions) and not effectiveness (how well an intervention works in everyday practice).

Historically, traditional sources of evidence included printed materials such as textbooks, personal journal collections, conference proceedings, and clinical guidelines, which may or may not have been based on well-conducted research. Colleagues, mentors, those considered experts in the field, and personal experiences also were a predominant source of information for treatment decisions.^{2–4} However, many of these sources fall into

weaker categories of evidence, or are not even considered evidence because they do not use a scientific process or a structured method for making objective observations. As health professions have adopted EBDM, they have increasingly emphasized use of sources of evidence that reduce bias. It is important to recognize that, in addition to support through scientific investigations or when there are no studies that address the specific question, the EBDM process also includes the clinician's experience and judgment, the patient's values and preferences, and the clinical circumstances. EBDM seeks to blend experience and values with best evidence.

There are two types of evidence-based sources: primary and secondary. **Primary sources** are original research publications that have not been filtered or synthesized, such as individual research articles. Primary research consists of both quantitative and qualitative research. Most of the research and literature related to EBDM refers to **quantitative research**, which focuses on establishing cause-and-effect relationships through testing a specific hypothesis and reporting the results in statistical terms. In comparison, **qualitative research** is exploratory and uses an interpretive, naturalistic approach that focuses on how individuals or groups view and understand their surroundings and construct meaning out of their experiences. Qualitative research investigates the why and how of decision making, and data are typically reported using narrative terms and not displayed mathematically in tables or graphs. For example, some participants in a focus group on oral cancer prevention and early detection reported, "They checked the inside of my cheeks and pulled out my tongue and felt my neck. They didn't tell me what they were doing."⁵ Table 3-1 summarizes the characteristics of quantitative and qualitative research approaches. Additional discussion is provided in the chapters that follow.

QUANTITATIVE PRIMARY RESEARCH: EXPERIMENTAL STUDIES

Experimental studies are those in which the researcher controls or manipulates the variables under investigation, such as in testing the effectiveness of a treatment. These studies are the most complex and include randomized controlled trials and controlled clinical trials.

Randomized Controlled Trial

The **randomized controlled trial** (RCT) provides the strongest evidence for demonstrating cause and effect (i.e., the treatment has caused the effect, rather than it happening by chance). An RCT study design involves the following.

- At least one test/experimental treatment or intervention and one control treatment that can be a placebo treatment or no treatment.
- Concurrent enrollment of subjects and follow-up of the experimental test- and control-treated groups.
- Assignment of subjects to either the experimental treatment/intervention group or the control/placebo group through a random process, such as the use of a random-numbers table.
- Follow-up of both groups to determine the outcome.

The most important characteristics of RCTs are the ability to randomly assign subjects to either the experimental or control group and to randomly allocate treatments. Other unique features of RCTs that reduce bias and strengthen validity are that they are prospective in nature and can include blind or double blind strategies. A **double-blind RCT** is one in which neither the patient nor the investigator knows whether the patient is receiving the experimental treatment or the control treatment. Studies involving therapies (pills/liquids/pastes) are easy to double-blind because the subject takes one of two treatments of identical size/dose, shape, and color, and neither the patient nor the investigator knows who is taking the treatment or the placebo. It is more difficult to double-blind studies when testing a new treatment, technique, or procedure in which the investigator or patient can distinguish a difference. In these studies, an examiner who has not been involved in the implementation of the study should be used to evaluate the results to decrease bias.

Nonrandomized Clinical Trials

Nonrandomized clinical trials often rely on historical controls that cannot establish true equivalence so that there is less confidence in the findings. For example, in cancer research, patients receive a new treatment and their responses are compared with controls from previous studies; however, the controls may not provide a good comparison depending on how long ago the study was conducted, or differences in treatment, technology, and patient care that have occurred since that time.⁸

Nonrandomized clinical trials also are used to screen new therapies. The purpose is not to prove the treatment is efficacious, but that there is sufficient activity to be tested in a randomized study. These studies require fewer patients; however, they are subject to investigator and placebo bias because all patients are treated in an unblinded manner.⁸ Finally, nonrandomized clinical trials, or **controlled trials**, may be used in diagnostic studies in which the outcomes from a new test under evaluation are compared with outcomes from the reference or **gold standard test** (i.e., the test or measure considered the ultimate or ideal). In controlled trials, there is no

TABLE 3 – 1

Characteristics of Quantitative and Qualitative Research Approaches^{6,7}

	Quantitative		Qualitative
	Experimental	Nonexperimental	Nonexperimental
Purpose and study design	Begins with hypothesis and tests cause and effect; variables are defined and manipulated. Answers questions related to therapy and harm in terms of how many or how much; probability sampling allows generalizing findings, uses a deductive process Double- or single-blinded RCTs or nonblinded RCTs or controlled trials	Observational studies used to systematically describe and interpret conditions/relationships that already exist. Examines the association between a particular exposure and a risk factor; or between a disease and hypothesized risk factors. A treatment or intervention is not given Cohort, case control and case series, or report studies	Uses a naturalistic approach to answer questions about the meaning, or attitudes, beliefs, or behavior of a group or individual; provides explanation and understanding; uses an inductive process; used to generate hypotheses Phenomenology, ethnography, and grounded theory
Data collection	Systematic data collection using predefined methods of measurement. Often have blinding of examiners to minimize bias when examining experimental and control groups	Gathers data without giving a treatment or intervening to control variables; clinical exam, survey, or questionnaires. Can be collected once or multiple times over time	Fieldwork to observe people and record in the natural setting. Data collected via focus groups, observation, unstructured interviews, diaries, written anecdotes, philosophy, poetry, or art
Role of researcher	Tends to remain separate from the subject matter		Tends to be immersed in the subject matter; personal involvement
Analysis	Analysis occurs after all data are collected. Involves analysis of numerical data that can be combined and manipulated using statistical methods. Results reported using numerical relations and statistical terms		Analysis takes place concurrently with data collection and is ongoing. Involves analysis of thoughts or concepts, pictures, or objects and categorized into themes. Reported in narrative terms

randomization because *both tests are given to all individuals* who are suspected of having the condition of interest, and measurements from each test are compared to determine if the new test is as accurate as the reference or gold standard test.⁹

QUANTITATIVE PRIMARY RESEARCH

Nonexperimental Studies

Nonexperimental studies are those in which the researcher does not give a treatment, intervention, or provide an exposure (i.e., data is gathered without intervening to control variables). Examples of nonexperimen-

tal studies include cohort studies, case control studies, case series, and case reports.

Cohort Studies

Cohort studies make observations about the association between a particular exposure or a risk factor (e.g., tobacco use) and the subsequent development of a disease or condition (e.g., lung cancer). In these studies, subjects do not presently have the condition of interest (lung cancer) and are followed over time to see at what frequency they develop the disease/condition as compared with a control group who is not exposed to the risk factor (tobacco use) under investigation (Fig. 3-1).

As in experimental studies, both groups are followed prospectively and there is the ability to establish



Persons with and without the **exposure** of interest (e.g., tobacco) are identified at the initiation of the study. Information is then collected looking forward in time to identify outcomes (i.e., disease [lung cancer] or no disease). At the start of the study, neither group has the disease or condition of interest.

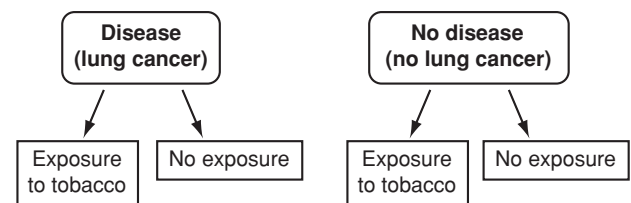
FIGURE 3-1 Prospective cohort study design.

a temporal sequence for the relationship between exposure to risk factors and development of a particular disease or condition.¹⁰ The temporal sequence (i.e., the exposure has to precede the development of the disease/condition) is necessary for drawing inferences about causative factors. The important advantage of this design is the ability to control and monitor data collection and to measure variables accurately.

A cohort study is most useful when the disease/condition of interest occurs frequently and subjects can be readily obtained. It also is useful when the risk factors are known or thought to cause harm (tobacco use) and when there are ethical considerations. For example, researchers could not conduct an experimental study to determine if tobacco use causes lung cancer. This would require that subjects (all nonusers of tobacco) be randomly assigned to an experimental or control group and have those in the experimental group start smoking “x” number packs of cigarettes per day. Instead, investigators find people who already smoke “x” number packs of cigarettes per day (and who do not have lung cancer) and match them with as similar a group as possible, with the exception of not smoking, to serve as the control group. Both groups then are followed over time and the incidence of lung cancer in those who smoke is compared with the incidence of lung cancer in those who do not smoke. Obvious disadvantages are the time it could take to develop the disease or condition of interest (lung cancer), the cost of follow-up, and the potential for losing subjects over time.

Case Control Studies

Case control studies make observations about possible associations between the disease of interest (lung cancer) and one or more hypothesized risk factors (tobacco use).¹⁰ Case control studies are retrospective in that subjects *already have a certain disease or condition* and are compared with a representative group of disease-free people (controls) from the same population (Fig. 3-2).



Persons with and without the **disease** of interest (e.g., lung cancer) are identified at the initiation of the study. Information is then collected looking backward in time to identify potential exposure or risk factors (e.g., tobacco) that could have contributed to getting the disease.

FIGURE 3-2 Case control—retrospective study design.

A case control study is most useful in studying the etiology of rare diseases because they are difficult to study on a population basis. Also, a case study allows multiple etiologic factors to be studied concurrently.¹⁰

The problem with case control studies is that investigators are looking back in time and often have to rely on the subjects’ recall or other incomplete sources of information for exposure histories or characteristics that could have put a person at risk for developing the condition or disease of interest. The assumption is that the differences should explain why the cases developed the condition/disease of interest and the controls did not. Although simplified, using the tobacco and lung cancer example, lung cancer patients would be asked questions related to their smoking history. For example, do they currently smoke, or have they every smoked and, if so, when did they started smoking, how much do they smoke, when did it increase and by how much; did they ever stop and then start again and when; and their answers would be compared with those of the control group. As a result, this study design lends itself to recall bias and extraneous variables more so than a cohort or experimental study. Case control studies also are less reliable because a statistical relationship between two conditions does not mean that one condition actually caused the other. For instance, lung cancer rates may be higher for people who earn less than \$50,000 per year, but that does not mean that someone can reduce his or her cancer risk just by getting a salary increase to more than \$50,000. When possible, researchers should confirm the results with a randomized controlled trial or a prospective cohort study.

Case Series and Case Reports

Case series and case reports are often reported in the dental and dental hygiene literature. These consist either of collections of reports on the treatment of several patients, or a report of a single patient. For example, if a patient has a condition that a clinician has never seen or heard of before and is uncertain what to do, a search for

case series or case reports may reveal information that will assist in a diagnosis. However, for any reasonably well-known condition, there should be better evidence. Case series and case reports have no statistical validity, because they report observations and do not use a control group with which to compare outcomes. However, they can be extremely important in identifying new health concerns and often generate a hypothesis that then sparks the initiation of more rigorous prospective studies and clinical trials as they did with toxic shock syndrome¹¹ and AIDS.¹²

QUALITATIVE PRIMARY RESEARCH

Qualitative research is nonexperimental in that it conducts studies in natural settings in an attempt to understand an event from the point of view of the participants. It seeks to provide depth of understanding and does so through answering questions such as what, how, and why. It explores issues in more depth with those experiencing the issue rather than testing a hypothesis to answer questions such as how many or what proportion.

In many cases, qualitative research generates new theory. Also, it complements quantitative research by attempting to clarify the meaning of how many or by providing a greater understanding of why an intervention works. For example, quantitative research may ask, “How many smokers have tried to quit?” whereas qualitative research explores “What stops smokers from quitting?” The most important consideration in designing a study is to use the right methodology to answer the question.

Good qualitative research requires a very rigorous design. Criteria include: stating a clear aim of the research, which includes both context and process, and documenting transferability (a detailed description of the sample and findings so that similarities and differences can be identified); dependability (clear records of the research process and its products); confirmability (conclusions are fair so that there is confidence in the findings; multiple data sources are used); and credibility (internal validity—do the findings make sense).⁶

Qualitative research has many different research designs and data collection methods based on the questions being explored and the setting being observed. Three common study designs include: ethnography, phenomenology, and grounded theory. Ethnography asks, “What is the culture of a group of people?” and collects data through participant observation, unstructured interviews, and studying documents and photographs. Culture is not limited to ethnic groups, but may involve organizations, programs, and groups of people with common social or health problems. Phenomenology answers

the question, “What is it like to have a certain experience?” and collects data through in-depth interviews, written anecdotes, philosophy, poetry, or art. Examples of experiences include those related to emotions, relationships, or to being part of an organization or group. Grounded theory builds on the inductive nature of qualitative research and focuses on theory construction and verification by studying interactions as they occur naturally. Data collection methods include taped interviews, participant observation, focus groups, and diaries. Tables 3-2 and 3-3 provide further information related to the focus of each study design and the correct data gathering method used to generate the data to answer the research objective.

SECONDARY RESEARCH: SYSTEMATIC REVIEWS AND META-ANALYSIS

Secondary research is filtered or synthesized publications of the primary research literature. These sources include systematic reviews (SRs) and meta-analyses, evidence-based article reviews of already conducted research, and evidence-based clinical practice guidelines.

With more than 2 million articles published annually and 20,000 biomedical journals, SRs provide a way of managing large quantities of information¹³ by providing a summary of two or more primary research studies that have investigated the same specific phenomenon or question. This scientific technique defines a specific question to be answered and uses explicit predefined criteria for retrieval of studies, assessment, and synthesis of evidence from individual RCTs and other well-controlled methods. Methods used in SRs parallel those of RCTs in that each step is thoroughly documented and reproducible. For example, there are predefined criteria for the inclusion and exclusion of research studies in an SR just as there are predefined criteria for the inclusion and exclusion of subjects in an individual RCT. Figure 3-3 demonstrates how individual research studies contribute to building a body of

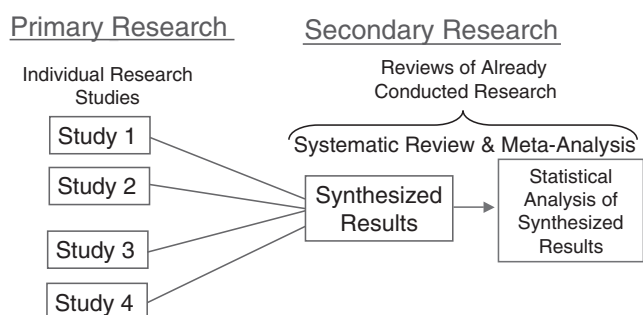


FIGURE 3-3 Differences between primary and secondary sources.

TABLE 3 – 2

Qualitative Research Paradigms					
<div> Criteria → <div> ↓ </div> </div> Paradigms (Research Strategy)		Research Questions <i>(but Do not Restrict the Inquiry)</i>	Methods of Data Gathering and Analysis Consistent With Philosophical and Epistemological Traditions from Which They are Derived and are Compatible with the Type of Question being Asked	Methods of Data Gathering and Analysis are Rigorously and Appropriately Applied Describes: How Participants Selected Methods Used to Generate Data Comprehensiveness of Data Collection Procedures for Analyzing Data	Thoughtful and Ethical Plan For Entering the Field of Study, Establishing and Maintaining Relationship and Exiting the Field is Illustrated
Phenomenology Describes lived experiences of individuals as interpreted by the researcher. (Philosophy)	What is the meaning of the phenomenon? What is it like to have a certain experience? Can be related to emotions, relationships, part of an organization or group.	In-depth interviews, written anecdotes, philosophy, poetry or art. Experience provided direction of the study.	Presented examples of research questions.	Identified people, the use of art, poetry, etc.	Conclusions are Based Upon Research Results. Data Analysis is Systematic and Meaningful.
Ethnography Used to study people of other cultures. (Cultural anthropology)	What is the nature of this phenomenon? What is the culture of a group of people? Culture may be an ethnic group, organization, program, group of people with common social or health problems.	Participant observation, unstructured interviews, documents, photographs. Researcher learns from participants the meanings they attach to activities, events, behaviors, knowledge, rituals and lifestyle.		Participants and observers of participants	Reflective description of the experience: "What it felt like to..." Researcher's bias and influence of their own point of view is stated and discussed within the context of the study
(Continued)					

TABLE 3 – 2

(Continued)

<div>Criteria →</div> <div>↓</div> <div>Paradigms (Research Strategy)</div>	<div>Research Questions Guide (but Do not Restrict) the Inquiry</div>	<div>Methods of Data Gathering and Analysis Consistent With Philosophical and Epistemological Traditions from Which They are Derived and are Compatible with the Type of Question being Asked</div>	<div>Methods of Data Gathering and Analysis are Rigorously and Appropriately Applied Describes: How Participants Selected Methods Used to Generate Data Comprehensiveness of Data Collection Procedures for Analyzing Data</div>	<div>Thoughtful and Ethical Plan For Entering the Field of Study, Establishing and Maintaining Relationship and Exiting the Field is Illustrated</div>	<div>Conclusions are Based Upon Research Results. Data Analysis is Systematic and Meaningful.</div>
Grounded Theory Discovers basic patterns in social life to generate theories. Used for conceptualizing. (Sociology)	What are the interactions or processes going on? Does not start with a specific research question. Researcher begins study by looking at underlying social and psychological processes that relate to conditions in a particular setting	Taped interviews, participant observation, focus groups, diaries. Studies interactions as they occur naturally.	Researcher identifies key variable that explains what is occurring and further develops emerging theory. Lit review occurs after researcher identifies emerging theory. Data analysis compares emerging theory with existing research (theories).	Key people who play specific roles	Theory development with respect to social and psychological processes. Theory is developed or reformulated from the existing source. Researcher's bias and influence of their own point of view is stated and discussed within the context of the study.

McMaster; <http://www.cche.net/usersguides/qualitative.asp>

Mita Giacomini, Deborah J. Cook, for the Evidence Based Medicine Working Group. Based on the Users' Guides to Evidence-based Medicine and reproduced with permission from JAMA. (2000 Jul 26;284(4):478–482) Copyright 2000, American Medical Association.

TABLE 3 – 3

Qualitative Research Methods

<i>Methods</i>	<i>Rationale</i>	<i>Nature of Research Questions</i>	<i>Sampling No. and Group Composition</i>	<i>Recording Data</i>
Observation Overt or covert	Natural setting; can overcome discrepancy between what is said and what is actually done Want to communicate cultural values of setting Can identify processes of which people are unaware	Answers why; observing working of organizations and how people perform functions Cultures	Purposive; deliberate group or setting; not generalizable; Should select a good representational setting with features and categories relevant to a wide range of settings	Systematic recording of field notes. May ask questions or analyze documents. Looking especially for tentative hypotheses and negative cases.
Interviews 1) Structured-questionnaire 2) Semistructured 3) In depth	Explore people's knowledge, experiences and framework of meanings	To understand practices and discover factors that contribute to situation. How and why phenomena occur	Determined by nature of research; purposive sampling. Statistical representation not sought. Sample size determined by depth and duration of interview and what is feasible Large study may have 50–60 at most	Tape recorder: transcription is time consuming. Field notes at time of interview interferes with process; afterwards may forget or miss some details
Focus Groups Group interviews	Capitalize on communication among participants in order to generate data. Interactions are part of method. Highlight values and norms of culture (e.g., why or why not they use health services).	What people think, how they think and why they think that way. Exploring responses to health education messages, public understanding of health and illness. Health behaviors, experiences with disease and health services; attitudes and needs of staff	Most include few groups; 4–8 people is ideal; 1–2 hours Homogeneous groups capitalize on shared experiences. Existing groups → naturally occurring setting can relate or challenge each other. Theoretical sampling with subjects selected to represent range of total study population or to test hypotheses. Diversity may be needed to explore different perspectives.	Taped and transcribed; series of statements on cards; questionnaire. Group records issues on flip chart

(Continued)

TABLE 3 – 3

(Continued)

<i>Methods</i>	<i>Rationale</i>	<i>Nature of Research Questions</i>	<i>Sampling No. and Group Composition</i>	<i>Recording Data</i>
Case Study 1) Precise questions during data collection and analysis (allows comparisons) 2) Study implemented empirically	Practical and policy questions; health services research (HSR) Understand principles guiding design and conduct of evals; Involves complex mix of changes, different time scales, involvement of different groups (providers, admin); Study implementation of health policies empirically versus analyzing proposed projects analytically Retrospective or prospective	Real life intervention focus Semistructured; ethnography-eventually research questions emerge; research → impact of government policies in health system Forming judgments about appropriateness of an intervention. Investigate how and why it succeeded or failed; whether outputs and outcomes of intervention are justified by their inputs and processes	Sites typical of phenomena being studied Those in which a specific theory can be tested or a hypothesis; Replication of results across sites → ensure findings not due to site characteristics	Depends on methods chosen. Researchers want to build chains of evidence-conceptual arguments that link phenomena to one another.
Consensus Methods	Method to synthesize info using wider range of information than meta-analysis. Determine extent to which experts or lay people agree about a given issue	When need to make decisions where there is little or conflicting evidence or overload of information. For clarifying issues in organization or defining professional roles Unanimity of opinion does not exist owing to lack of scientific evidence or where there is contradictory evidence on an issue	Experts, relevant individuals Delphi: conducted by mail	Defined structured process for conducting, tabulating and providing results/ratings back to participants
1) Delphi technique	Where published information is inadequate or nonexistent	Unanimity of opinion does not exist owing to lack of scientific evidence or where there is contradictory evidence on an issue	Delphi: conducted by mail	
2) Nominal Group Process	Harness insights of appropriate experts to enable decisions to be made Deriving quantitative estimates through qualitative approaches	Consensus measurement and consensus development	Nominal: conducted in person; 9–12 people	

(Continued)

TABLE 3 – 3

(Continued)

<i>Methods</i>	<i>Role of Researcher</i>	<i>Analysis or Interpretation</i>	<i>Advantages</i>	<i>Limitations</i>
Observation Overt or covert	Researcher to act as research instrument and documenter necessary that observations are systematically recorded and analyzed; record own feelings and responses to situation witnessed. Needs to be able to establish rapport May be involved in activities while also observing them	Iterative process of developing categories from notes, testing against hypotheses and refining. Basis of tentative hypothesis or evolution of systems classification Not distinct stages but occurs with data collection Validity: truthful and systematic representation of research; communicate culture and rules enough to allow another researcher to learn them and pass as a member of the group	Uncover behavior or routine of which participants may be unaware; overcome discrepancies between what is said and what is done Can build on quantitative research → understanding of why	Researcher behavior immersion Hawthorne effect Gaining access to group Going “native” Large amounts of data to analyze Reliability and validity, generalization Researcher may not observe what they really want to see
Interviews 1) Structured-questionnaires 2) Semistructured 3) Indepth	Discover interviewees own framework of meanings; must avoid imposing own structures and assumptions; remain open to new concepts that may be very different than predicted	Transcription of data after collection; can influence refinement of questions for next interview	Can probe and explore issues in depth to get to the bottom of what you want—better than observation. Can open up new areas of research; investigate questions of immediate relevance	Skills of interviewer; must be sensitive to vocabulary of interviewee; People do not do what they say all the time Problems with recall, bias and selective remembering Hard to categorize and summarize data that researcher has: 1) understood respondent’s meaning instead of relying on their own assumptions; 2) the questions are neutral, sensitive, clear

(Continued)

TABLE 3 – 3

(Continued)

<i>Methods</i>	<i>Role of Researcher</i>	<i>Analysis or Interpretation</i>	<i>Advantages</i>	<i>Limitations</i>
Focus Groups Group interviews	Facilitate interaction among members of the group	Compares discussions of similar themes; distinguish between individual opinion and group consensus. Report deviant cases, minority opinions; impact of group dynamics and interaction between participants	Does not discriminate against people who can not read or write. Encourages participation from people reluctant to be interviewed on their own feelings or believe they have nothing to say. Can empower; safety in numbers.	Can lack confidentiality Dominant views may silence other group members Data analysis is time consuming
Case Study 1) Precise questions during data collection & analysis (allows comparisons) 2) Study implemented empirically	Multiple methods used Semi-structured interviews; focus groups, observations	Multiple methods and sources of evidence to establish construct validity Triangulation: at least 1 other source and usually another method of data collection Explain quantitative findings, e.g., explain why there was an increase or decrease in number of referrals, number of admissions	Complexity of issues—evaluation of health services interventions Answer how and why events take a particular course	Complex Single coherent account of events can vary widely Site selection can be difficult Multiple methods are hard to manage Evaluation to inform policy requires overall judgement of success or failure
Consensus Methods 1) Delphi technique 2) Nominal group process		Agreement: 1) extent to which each respondent agrees with an issue-numerical scale 2) extent to which respondents agree with each other = consensus; average + dispersion	<i>Delphi:</i> Confidentiality; One person or coalition is not able to dominate Iterative process allows participants to change minds Controlled feedback Statistical group responses Large number of experts can be contacted cheaply	Justification of these methods Potential for bias in selection of experts. Difficult to define “acceptable” levels. Typical disadvantage of group decision-making. Presentation of findings; testing findings against observed data.

knowledge¹⁴ and the difference between primary and secondary sources.

Systematic reviews differ from traditional literature or narrative reviews in that they are narrower in scope and focus on answering specific questions. Those conducting SRs try to find all the literature addressing a specific question, including unpublished or “gray” literature. The gray literature may include reports, working papers, theses/dissertations, government documents, conference proceedings, or meeting abstracts, all of which do not result in a journal article publication, thus making them more difficult to identify. Studies selected for inclusion in an SR must meet specific predefined criteria, such as the type of research design used, sample selection, length of study, and outcome variables of interest. The identification of RCTs to include in a systematic review is an indirect measure of the availability (or lack thereof) of multiple high-quality studies in a given area. In contrast, a traditional literature or narrative review serves a different purpose in that it deals with a broad range of issues on a given topic rather than answering a specific question in depth. Literature reviews also provide a more subjective assessment in that literature can be selected to support a desired conclusion.¹⁵ A comparison of SRs and literature reviews is illustrated in Table 3-4.

An example of a well-conducted systematic review is demonstrated in the detail of the outline of a Cochrane Systematic Review, as seen in Table 3-5.

Meta-analysis is a statistical process commonly used with systematic reviews. It involves combining the data from multiple individual studies into one analysis. Often smaller RCTs may have rigorous designs but lack

the statistical power to demonstrate a statistically significant effect. When data from these studies are pooled, the sample size and power usually increase. As a result, the combined effect can increase precision of estimates of treatment effects and exposure risks,¹³ more so than a SR review in which the data cannot be statistically combined and analyzed.

SECONDARY RESEARCH

Evidence-Based Journals and Article Reviews

Many evidence-based resources have been and are continuing to be developed by evidence-based groups for busy practitioners in order to facilitate the integration of evidence into their clinical decision-making. These include **evidence-based journals** (e.g., *Journal of Evidence Based Dental Practice (JEBDP)*, *Evidence-Based Dentistry (EBD)*, *Evidence-Based Medicine*, *Evidence-Based Nursing*, and *Evidence-Based Healthcare*) and online resources. These journals provide concise and easy-to-read summaries of original and review articles selected from the biomedical literature based on specific inclusion criteria. **Article reviews** of already conducted research often consist of a one- to two-page structured abstract along with an expert commentary highlighting the most relevant and practical information of the study being reviewed.

Evidence-Based Clinical Practice Guidelines

Clinical practice guidelines are a growing source of synthesized information on a specific topic. As defined by the Institute of Medicine, guidelines are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”¹⁶ The inclusion of scientific evidence within clinical practice guidelines has now become the standard in that guidelines should incorporate the best available scientific evidence. SRs support this process by putting together all that is known about a topic in an objective manner. Examples of clinical practice guidelines include the American Dental Association’s clinical recommendations on professionally applied topical fluoride,¹⁷ the American Association of Periodontology’s guidelines on the management of patients with periodontal disease,¹⁸ and the American Dental Hygienists’ Association’s guidelines on polishing procedures.¹⁹

CONCLUSION

As EBDM becomes standard practice, individuals must be knowledgeable of what constitutes the evidence

TABLE 3 – 4

Cochrane Systematic Review Outline

1. Synopsis
2. Abstract
3. Objectives
4. Criteria for selecting studies:
 - Types of participants
 - Types of intervention
 - Type of outcome measures
 - Types of studies
5. Search strategy
6. Description of studies
7. Methodological quality
8. Results
9. Discussion
10. Reviewers conclusions
11. Acknowledgments
12. Conflicts of interest
13. References
14. Tables and figures

TABLE 3 – 5

General Characteristics of Systematic Reviews and Traditional Narrative Reviews of the Literature

Characteristic	Systematic Review	Traditional Narrative Review of the Literature
Focus of the review	<ul style="list-style-type: none"> • Specific problem or patient question; • Narrow focus • Example: Effectiveness of fluoride varnish as compared with topical SnF fluoride in preventing root caries 	<ul style="list-style-type: none"> • Range of issues on a topic • Broad focus • Example: Measures for preventing root surface caries; can include many types of fluorides; may not make comparisons between methods
Who Conducts	<i>Multidisciplinary Team</i>	<i>Individual</i>
Selection of studies to include	<ul style="list-style-type: none"> • Prestablished criteria based on validity of study design and specific problem • All studies that meet criteria are included • Systematic bias is minimized based on selection criteria 	<ul style="list-style-type: none"> • Criteria not preestablished or reported in methods. Search on range of issues • May include or exclude studies based on personal bias or support for the hypothesis, if one is stated. • Inherent bias with lack of criteria.
Reported findings	<ul style="list-style-type: none"> • Search strategy and databases searched • Number of studies that met criteria; number that did not meet and why studies were excluded • Description of study design, subjects, length of trial, state of health/disease, outcome measures 	<ul style="list-style-type: none"> • Literature presented in literature review format and crafted by the individual author • Search strategy, databases, total number of studies pro and con not always identified • Descriptive in nature reporting the outcomes of studies rather than their study designs
Synthesis of selected studies	<ul style="list-style-type: none"> • Critical analysis of included studies • Determination if results could be statistically combined, and if so, how meta-analysis was conducted 	<ul style="list-style-type: none"> • Reporting of studies that support a procedure or position and those that do not rather than combining data or conducting a statistical analysis
Main results	<ul style="list-style-type: none"> • Summary of trials, total number of subjects • Definitive statements about the findings in relation to the specified objectives and outcome measures 	<ul style="list-style-type: none"> • Summary of the findings by the author in relation to the purpose of the literature review and specific objectives
Conclusions or comments	<ul style="list-style-type: none"> • Discussion of the key findings with an interpretation of the results, including potential biases and recommendations for future trials 	<ul style="list-style-type: none"> • Discussion of the key findings with an interpretation of the results, including limitations and recommendations for future trials

and how it is reported. Understanding evidence-based methodology and distinctions between different types of research allows the clinician to better judge the validity and relevance of reported findings. To assist practitioners with this endeavor, new journals devoted to evidence-based practice are being published that alert readers to important advances in a concise and user-friendly manner and the numbers of systematic reviews on clinically relevant topics are increasing. By integrating good science with clinical judgment and patient preferences,

clinicians enhance their decision-making ability and maximize the potential for successful patient care outcomes.

REFERENCES

1. Greenhalgh T. "Is my practice evidence-based?" Should be answered in qualitative, as well as quantitative terms. *BMJ*. 1996;313:957–958.
2. Hall E. Physical therapists in private practice: information

- sources and information needs. *Bull Med Libr Assoc.* 1995;83:196–201.
3. Gravois S, Bowen D, Fisher W, et al. Dental hygienists' information seeking and computer application behavior. *J Dent Educ.* 1995;59:1027–1033.
 4. Curtis K, Weller A. Information-seeking behavior: a survey of health sciences faculty use of indexes and databases. *Bull Med Libr Assoc.* 1993;81:383–392.
 5. Horowitz AM, Canto MT, Child WL. Maryland adults' perspectives on oral cancer prevention and early detection. *JADA.* 2002;133:1061.
 6. Giacomini M, Cook D. User's guides to the medical literature: XXIII. Qualitative research in health care A. Are the results of the study valid? *JAMA.* 2000;284:357–362.
 7. Giacomini M, Cook D. User's guides to the medical literature: XXIII. Qualitative research in health care B. What are the results and how do they help me care for my patients? *JAMA.* 2000;284:478–482.
 8. Albert P, Borkowf C. An introduction to biostatistics: randomization, hypothesis testing and sample size. In: Gallin J, editor. *Principles and Practice of Clinical Research.* San Diego, CA: Academic Press, Elsevier, 2002;163–185.
 9. Bossuyt P, Reitsma J, Bruns D, et al. The STARD statement for reporting studies of diagnostic accuracy: explanation and elaboration. *Clin Chem.* 2003;49:7–18.
 10. Manolio T. Design and conduct of observational studies and clinical trials. In: Gallin J, editor. *Principles and Practice of Clinical Research.* Academic Press, Elsevier, New York, NY, 2002:187–206.
 11. Davis J, Chesney P, Wand P. Toxic shock syndrome: epidemiologic features, recurrence, risk factors, and prevention. *N Engl J Med.* 1980;303:1429.
 12. Centers for Disease Control. Pneumocystis pneumonia—Los Angeles. *MMWR Morb Mortal Wkly Rep.* 1981;30:250.
 13. Mulrow C. Rationale for systematic reviews. *BMJ.* 1994;309:597–599.
 14. SUNY Downstate Medical Center. Guide to research methods, the evidence-based pyramid-systematic reviews and meta-analysis. SUNY Downstate Medical Center Web site. <http://library.downstate.edu/EBM2/2700.htm>. Accessed September 7, 2006.
 15. Sackett D, Haynes R, Guyatt G, et al. *Clinical Epidemiology: A Basic Science for Clinical Medicine.* 2nd ed. Boston: Brown & Company, 1999.
 16. Committee on Quality of Health Care in America, IOM. *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington DC: The National Academy of Sciences, 2000.
 17. American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride, evidence-based clinical recommendations. *JADA.* 2006;137:1151–1159.
 18. American Association of Periodontology. Guidelines for the management of patients with periodontal disease. American Association of Periodontology Web site. www.perio.org/resources-products/pdf/management.pdf. Accessed March 31, 2007.
 19. American Dental Hygienists Association. ADHA position on polishing procedures. American Dental Hygienists Association Web site. www.adha.org/profissues/polishingpaper.htm. Accessed March 31, 2007.

SUGGESTED ACTIVITIES

At this time, complete the quiz provided here. Then answer the critical thinking questions. Next, complete Exercise 3-1, which asks that you identify whether the described study design is quantitative, qualitative, experimental, nonexperimental primary research or secondary research.

QUIZ

1. Explain why a single research study does not constitute “the evidence.”

2. All of the following are considered primary sources of evidence EXCEPT:

- a. RCT
- b. Cohort study
- c. Meta-analysis
- d. Case report

3. Which of the following are considered a secondary source of evidence?

- a. RCT
- b. Cohort study
- c. Meta-analysis
- d. Case report
- e. Case control study

4. Experimental research differs from nonexperimental research in that it:

- a. Makes observations without intervening
- b. Focuses retrospectively
- c. Studies rare diseases
- d. Tests cause and effect
- e. Has no control group

5. Match the study design with its characteristic:

<u>Study Design</u>	<u>Characteristic</u>
a. Case control	_____ Prospective without any intervention
b. Cohort study	_____ Tests cause and effect
c. RCT	_____ Synthesis of two or more studies
d. Case report	_____ No control group
e. Systematic review	_____ Single patient observation

6. Characteristics of experimental research include:

- a. Randomizing subjects to treatment and control groups
- b. Randomly allocating treatments
- c. Ability to blind studies
- d. Retrospective analysis
- e. a, b, and c
- f. All of the above

7. Characteristics of nonexperimental research include:
- a. Making observations between exposures and diseases
 - b. Ability to conduct studies prospectively
 - c. Ability to conduct studies retrospectively
 - d. Reports of a single case
 - e. a, b, and c
 - f. All of the above
8. Match the type of research (A or B) with the characteristics list below.
- A. Qualitative research or B. Quantitative research
- _____ Tests a hypothesis
- _____ Provides explanations
- _____ Data are collected via fieldwork
- _____ Analysis occurs after all data are collected
- _____ Tests cause and effects
- _____ Examines associations between exposure and risk factor
- _____ Data reported in narrative terms
- _____ Can generate hypotheses

CRITICAL THINKING QUESTIONS

1. Discuss how quantitative and qualitative research are complementary and provide an example of a study related to patient problems that would include both types of studies. (Example: how often patients floss [quantitative study] and what barriers do they encounter that prevents them from flossing every day [qualitative study]).

2. Explain why an RCT is not always the appropriate research design to use.

3. Provide an example of when you would first conduct a traditional literature search before looking for a systematic review or meta-analysis.

EXERCISE 3-1

Identify whether the described study design is quantitative, qualitative, experimental, nonexperimental, primary research, or secondary research. Please check all that apply.

Check all that apply:

1. Randomly assigned subjects, randomly assigned treatments, experimental and control groups

- | | | |
|---------------------------------------|--|---|
| <input type="checkbox"/> Quantitative | <input type="checkbox"/> Experimental | <input type="checkbox"/> Primary research |
| <input type="checkbox"/> Qualitative | <input type="checkbox"/> Nonexperimental | <input type="checkbox"/> Secondary research |

2. Systematic statement to assist decision-making about care for specific circumstances

- | | | |
|---------------------------------------|--|---|
| <input type="checkbox"/> Quantitative | <input type="checkbox"/> Experimental | <input type="checkbox"/> Primary research |
| <input type="checkbox"/> Qualitative | <input type="checkbox"/> Nonexperimental | <input type="checkbox"/> Secondary research |

3. Compilation of data from multiple studies selected using explicit criteria that answers a specific question

- | | | |
|---------------------------------------|--|---|
| <input type="checkbox"/> Quantitative | <input type="checkbox"/> Experimental | <input type="checkbox"/> Primary research |
| <input type="checkbox"/> Qualitative | <input type="checkbox"/> Nonexperimental | <input type="checkbox"/> Secondary research |

4. Observes associations between risk factors and the development of a disease

- | | | |
|---------------------------------------|--|---|
| <input type="checkbox"/> Quantitative | <input type="checkbox"/> Experimental | <input type="checkbox"/> Primary research |
| <input type="checkbox"/> Qualitative | <input type="checkbox"/> Nonexperimental | <input type="checkbox"/> Secondary research |

5. Reports the treatment of a single patient or several patients with the same condition

- | | | |
|---------------------------------------|--|---|
| <input type="checkbox"/> Quantitative | <input type="checkbox"/> Experimental | <input type="checkbox"/> Primary research |
| <input type="checkbox"/> Qualitative | <input type="checkbox"/> Nonexperimental | <input type="checkbox"/> Secondary research |

6. A retrospective study that observes possible associations between a disease and one or more hypothesized risk factors

- | | | |
|---------------------------------------|--|---|
| <input type="checkbox"/> Quantitative | <input type="checkbox"/> Experimental | <input type="checkbox"/> Primary research |
| <input type="checkbox"/> Qualitative | <input type="checkbox"/> Nonexperimental | <input type="checkbox"/> Secondary research |

7. Describes real experiences of individuals as interpreted by the researcher

- | | | |
|---------------------------------------|--|---|
| <input type="checkbox"/> Quantitative | <input type="checkbox"/> Experimental | <input type="checkbox"/> Primary research |
| <input type="checkbox"/> Qualitative | <input type="checkbox"/> Nonexperimental | <input type="checkbox"/> Secondary research |

NOTES

[illegible]