Evidence-Based Methods and Tools

Tools and Methods for Evidence-Based Research in Dental Practice: Preparing the Future

Francesco Chiappelli, PhD, and Paolo Prolo, MD
UCLA School of Dentistry
Evidence-Based Group International, PNI Group, Inc.
UCLA School of Dentistry, Student Study Group for Evidence-Based Research in Dentistry

Neogita Neagos, MD
Evidence-based group International, PNI Group, Inc.
UCLA School of Dentistry, Student Study Group for Evidence-Based Research in Dentistry

Angela Lee
UCLA School of Dentistry, Student Study Group for Evidence-Based Research in Dentistry
UCLA Graduate Program in Oral Biology & Medicine

Dalia Bedair and Saman Delgodei
UCLA School of Dentistry, Student Study Group for Evidence-Based Research in Dentistry
UCLA pre-dental program

Edna Concepcion, Jennifer Crowe, Deborah Termeie, and Richard Webster
UCLA School of Dentistry, Student Study Group for Evidence-Based Research in Dentistry
UCLA School of Dentistry
Los Angeles, CA
ABSTRACT
The vast amount of information and research available in dentistry engenders an immense challenge for dentists to manage patients. The future of dental practice rests on the ability of professionals to learn essential strategies for reliably accessing and evaluating the most current and valid research development for the benefit of each individual patient. Evidence-based research in dentistry emerged as a systematic process of critically assessing the published evidence to determine the best treatment for any given patient. The process consists of 5 steps: 1) defining the research question; 2) searching for the pertinent published literature; 3) evaluating the research reports systematically; 4) forming a consensus statement of the best available evidence; and 5) evaluating its clinical relevance. Evidence-based dentistry relies on standard methodology and instruments for searching the available evidence, for analyzing the quality of research reports (ie, internal and external validity), and for evaluating the implications of the best available evidence for the dental community of professionals, patients, insurance carriers, and funding agencies. This article describes the principal tools and methods now available for evidence-based research in dentistry. We also propose avenues of future evolution for this emerging field of research in dental practice.

EVIDENCE-BASED RESEARCH IN DENTAL PRACTICE
Research is fundamental to the advancement of dentistry as a science. Research provides the process for breaching new frontiers, for entering and conquering new domains of knowledge, and for securing the development and testing of novel and improved modes of intervention for our patients. Research uses the scientific process to state hypotheses and to verify and test theories rigorously. Research is the quality control gate for our past and current understanding of psycho-biological phenomena and the stepping stone to our vision of future models of health and disease. Research is the most fundamental tool available to dentists to insure the validity of the biological principles that lay as foundations to the profession.

The outcomes of research produce new evidence that either confirms or challenges pre-existing models and principles. Research evidence is the mortar dentists and scientists need, require, and use to further the knowledge base of the clinical practice. Dentistry in the 21st Century flourishes on research evidence, lest it remain stagnant in perspective and models that are passé. Dental practice must increasingly rely upon the new frontiers in knowledge and understanding that research provides. This is critical, because, based upon the best available evidence at any given time, the most appropriate dental treatment is devised and administered to the patient.

Evidence-based research in dental practice is that approach of clinical dental practice that relies upon the best available evidence in the formulation of modes of intervention specific to the needs of each patient. If dentists are to rely confidently on evidence-based dental practice, then the various elements that determine its actualization must be well characterized and well understood, lest the process of evidence-based dentistry be undermined.

The need for evidence-based research in dental practice arises from the astonishing rate of growth of the research literature in dentistry. The average dentist has a limited amount of time that can be dedicated to the pursuit of updating knowledge by reading published research. Therefore, it is not surprising that an ever-growing schism separates those responsible for developing and testing novel and improved treatment interventions in dental practice from those who could use them on the patients. Clinicians often lack the sophistication in research methodology, design, and data analysis to assess critically the validity and the reliability of published research.

In an effort to correct these situations, the movement of evidence-based research in dental practice has emerged, following a similar successful effort in medicine. Specialized groups (eg, Cochrane Group) have begun to generate superb critical and systematic evaluations of the research literature in certain domains of dental practice. These reports go beyond the traditional literature reviews and emphasize the critical analysis of the articles’ methodology, design, and data analysis. They often, but not always and depending upon the data, incorporate meta-analytical techniques to subsume the statistical significance of the single reports under evaluation into one overarching statement of research outcome. These reports consistently pursue the translation of statistically significant results into clinically relevant findings. Indeed, the sole and principal aim of evidence-based research is to generate a statement of consensus among all the examined research articles with respect to the best available evidence.

The value of Cochrane-type systematic reviews cannot be underestimated: these works generate invaluable, high-quality, and most reliable updated statements of the evidence in dental practice. However, whereas Cochrane reports should produce the necessary bridge between dental research and dental practice, they are de facto impractical to the dentist and pragmatically of little help. Their major drawback is unquestionably their
bulkiness and the sophisticated nature of their style. To the dentist interested in evidence-based dental practice, these systematic reviews often seem to be academic reports for use in the domain of academic dentistry.

A novel paradigm is needed that will permit dentists to access the best available evidence. Tools and methods must be crafted and evaluated, designed to generate a reliable and valid assessment of the research literature for use by dentists and insurance companies for the ultimate benefit of the patients.8

The success of evidence-based dental practice depends upon the quality of the evidence and upon the validity and reliability of available tools and methods used to evaluate the evidence. It is both essential to the success of the practice and feasible, despite time and financial constraints, that dentists develop and acquire the necessary skills to determine what constitutes reliable versus unreliable research evidence.

Readers must be trained in the fundamentals of research and in the critical questions in oral biology and medicine. They must be professional individuals, scrupulously trained and eligible for State certification. Their role must be 1) to assemble the sample of dental research literature to be scrutinized, 2) to read and to synthesize this literature, and 3) to generate a consensus statement of the best available evidence readily available to the dentists in their practice.

Readers must have sound knowledge of the field of dentistry and a graduate degree in research methodology and biostatistics. Alternatively, they may be trained dentists with substantial theoretical knowledge and practical experience in research. They must hold professional status, lest their hire and associations cast a shadow of conflict of interest.9,10

It is also evident that dentists could benefit from the knowledge of simple tools and methods in evidence-based research to enhance and to strengthen directly their practice of dentistry. Cognizant of that fact, we propose a simple algorithm by which the interested dentist can establish the best available evidence and proceed into fully informed clinical decision making. This approach can be taught and acquired by students in training in dentistry and by professionals already successfully engaged in dental practice.

GUIDELINES AND PARAMETERS: METHODS, DESIGN, AND ANALYSIS

Research is not an end to itself. Rather, it is a process: a mode of thinking, an analytical approach to evaluating facts. As a process of asking questions, research is grounded on the quality of the research question posed. The research question must be feasible, interesting, novel, ethical, and relevant, and it must be stated precisely, directly, and succinctly. A well-written research article states the research question rather openly in the abstract and again in one of the last paragraphs of the introduction.

A research project of good quality is one whose outcome variable (ie, dependent variable) responds directly to the research question. The measurements obtained from the changes in the outcome variable as a result of an experiment of nature or an investigator-driven manipulation—referred to, in both instances, as the independent variables—must be trustworthy, in the sense that they need to be reliable and valid. Experiments of nature are studied by means of observational designs, whereas the outcomes of manipulations are examined through experimental designs. Clinical trials are experiments that involve clinical treatment manipulations on patient samples. Not all dental research involves patient samples, but issues pertaining to the process of sampling are critical to any dental research.11,12

Well-reported research presents concerns about the limitations of observational and experimental designs, about problems of sampling (eg, lack of randomization), or about issues of measurement reliability or validity. Published reports ought to discuss the stringency (ie, reproducibility) of the research (ie, internal validity) or the generalizability of its conclusions (ie, external validity). Weaknesses that are inherent to the design and the methodology used to answer the research question can seriously threaten the study’s efficacy in obtaining a statistically strong outcome (contiguous in meaning to internal validity) and the study’s effectiveness in producing a clinically relevant finding (parallel in meaning to external validity).

The ultimate purpose of research is to quantify. The process of quantification allows a better understanding of fundamental biological mechanisms of oral health and disease, psycho-social behaviors of patients and practitioners, effectiveness of new treatment and materials, public health policy issues, the characteristics of new dental materials, and the like. The dependence of research on the process of quantification carries with it the reliance of the interpretation of the research outcome by means of the appropriate analysis of the data. Research data that are correctly analyzed lead to the formulation of statistical inferences (ie, conclusions), which tell us the probability (p) that the observed outcome occurs by chance alone. When this probability is low, the inference is made that the experiment of nature or the experimenter’s manipulation produced an outcome of marked and significant importance. Two caveats must not be ignored at this juncture: first, these probabilities must be compared with some point of
reference, the level of significance (\(\alpha\)), which holds a clear role in statistical theory that needs not be explored here; second, there is no off-hand relationship between what researchers find as statistically significant (ie, \(p < \alpha\)), and what the clinician in dental practice wishes to regard as clinically relevant. That very point is, in fact, the bridge that evidence-based research is protracted to establish: it is the very crux of the future development and establishment of this field of endeavor in the dental profession.

In summary, the process of evidence-based research in dental practice seeks to identify the best available evidence for the benefit of each individual patient. It derives its findings from the careful and systematic evaluation of the published research literature. This literature suffers an inherent bias in that there is a general tendency on the part of the scientific community to ignore research that shows no statistically significant data, regardless of its clinical relevance. Another difficulty in evidence-based research lies in the fact that it rests on findings that are obtained and analyzed on groups whose sample size often drives statistical significance; but evidence-based research pertains to the best available evidence in the treatment of individual patients.

Evidence-based research has elaborated the concept of Number Needed to Treat (NNT) in an attempt to translate the research data into information useful in practice. In a certain sense, this value can be seen as the reverse of the sample size and Power analysis, upon which rest the process of statistical inference.\(^{13}\)

Evidence-based research entails the critical examination of published research. It is a systematic process that follows the scientific method. It is research on research. Evidence-based research examines critically the strong and the weak points in the published reports’ methodology, design, and data analysis. It seeks to quantify these outcomes in a manner that permits further analysis along acceptable sampling theory. The process strives to the generation of a qualitative statement, the consensus statement, of the best available evidence for later incorporation by the clinician into the clinical decision-making process.

**INSTRUMENTS AND TOOLS IN EVIDENCE-BASED RESEARCH**

Three epochs have characterized the evolution of the tools and methods in evidence-based research in dental practice. Early in the last decade, and based upon the assumption that the ultimate model of research in dental practice was the clinical trial, standards for the evaluation of trials were established and soon accepted under the CONSORT acronym (consolidated standards for randomized trials). The Jadad scale\(^{14,15}\) was soon devised (Appendix 1) with the intent to provide some degree of quantification of 3 among the principal issues of concern in clinical trials: sample randomization, blinding, and subject drop-out. It was also soon recognized that the process of evidence-based research often involved the overarching analyses of the statistical findings by the techniques of meta-analysis and meta-regression. Therefore, standards were developed to ensure the quality of reporting of meta-analyses (ie, QUORUM). As the process of evidence-based research became increasingly established as a domain of research proper, it required a structured set of criteria for asking the research question in evidence-based dental practice. It was established that the fundamentals of evidence-based research must rest on the identification of a) the Problem (or patient) population (ie, who is to be treated), b) the Intervention under study (ie, what is being evaluated), c) the Comparison groups (ie, who is being tested and compared with what placebo group), and d) the Outcome (ie, what is being measured). The acronym PICO has come to signify the research question of the evidence-based research process.\(^3\)

It soon became apparent that research in dental practice is often concerned with predictive outcomes (eg, how will the patients fare in the future, as a consequence of the treatment). Therefore, evidence-based research now also considers the PIPO research question (eg, population, intervention, prediction, outcome). Furthermore, the concern arose as to the consistency of the critical evaluation of research reports across trained readers (ie, reliability). The Fresno test of evidence-based medicine\(^{16}\) was developed and characterized for this purpose. The test, which has an overall reported inter-rater reliability of 0.97 and a strong content and construct validity was adapted for dentistry (Appendix 2). In addition, the need arose to quantify the quality of the research abstract\(^{17}\) and of the body of the article.\(^{12}\) It must be stressed that neither tool seeks to go beyond the systematic and critical evaluation of the research methodology, design, and data analysis. The concern of each instrument is not to evaluate the science of dentistry in each report, but rather the science of the research. One approach consists of the What-Who-How (ie, WWH) scale, which guides the reader in the proactive reading of the research component of the article by asking 9 specific questions (Appendix 3). The questions pertain directly and uniquely to the study’s methodology, design, and data analysis. The reader gives both a quantitative score, and a short qualitative assessment for each question. Content validity of the WWH scale was reflected by the nature of the content of each of the
items, with the Jadad (CONSORT) and the Timmer scale (quality of abstracts scale) as reference. The criterion validity of WWH against the Jadad scale is high (0.94, \( p < .05 \)). The inter-rater reliability of WWH was 0.89 (\( p < .05 \)); its internal consistency was satisfactory as well (0.85, \( p < .05 \)). The Cohen \( k \) coefficient of agreement for WWH (\( k = 0.80; p < .05 \)) established that the degree of attained agreement was beyond chance (\( \alpha = 0.05 \)). The last question—how were the data analyzed?—refers to a newer criterion of evidence-based research evaluation that rests on the realization that research whose data analysis is flawed produces flawed conclusions, which ought not be used in any clinical decision. Hence, the acronym for the systematic evaluation of the statistical analysis (ie, SESTA) of the data was introduced. Both the Timmer and the WWH scales generate individual scores about the research methodology, design, and data analysis as well as a composite score.

In summary, the second epoch of expansion, establishment, and evolution of evidence-based research in dental practice has led to the development and characterization of key tools for reliable and valid research on research. Taken together, these instruments have formalized a systematic and reproducible process that has at its core methodological consistency that can be easily taught. In brief, the process of research on research in dental practice can be outlined as consisting of 5 steps: 1) A domain of inquiry for evidence-based research is identified, and a succinct, direct and precise PICO (or PIPO) question is formulated. 2) On the basis of the elements of the question, the broadest possible search of the published literature is obtained (ie, National Library of Medicine, PubMed, Medline, Ovid, etc.). Published communications in foreign languages are included if at all possible, because any restriction of the search process signifies a sampling selection bias, which, as noted above, threatened the validity of the research endeavor. 3) All of the identified research articles must be evaluated in a systematic review. When that is not feasible, as, for instance, because of the dentist’s time and manpower restriction, then a random sample of no less than 10% of the identified reports should be examined in what is called a best-case study. Published research articles are examined for the quality of the abstract by the Timmer scale, and a Jadad score is obtained if applicable; that is, when the report describes a clinical trial. The WWH scale further analyzes each research communication, and in this context, if the report is not a clinical trial, then the NNT question is not applicable, and the WWH score should be adjusted appropriately. The WWH scale requires a brief comment for each question, which serves as qualifier of the score and a more extensive summary critical evaluation of the article. 4) Taken together, these critiques and evaluations are pooled into a synthesis of the current state of knowledge, which is referred to as the consensus statement of the best available evidence. 5) This evidence is discussed from the perspective of clinical relevance, used in the clinical decision-making process, integrated into clinical practice, and evaluated by the dentist in practice.\(^6,12\)

We are now in the third epoch in the evolution of the tools and methods in evidence-based research in dental practice, which witnesses further evolution, expansion, and establishment of these fundamental concepts. It has now been recognized that research in oral biology and medicine does not and cannot yield an ultimate end. It is a process that leads to clinical trials, which are not the ultimate end of research. Clinical trials represent one piece—certainly a most important piece—of the complex and elaborate puzzle of research in dental practice. Materials research, bench research, and animal research are critical to developing, conducting, and interpreting clinical trials. In the same vein, the outcomes of clinical trials produce crucial information in forging the next cutting-edge question, which often can only be addressed by materials, laboratory, or animal research. It is now clear that, in its truest sense, research in dental practice is translational research, which implies a process whereby information freely flows from the laboratory to the dental chair and from the chair to the experimental laboratory setting. Research in dental practice is an upward mobile spiral, not a stagnant pyramid-like structure, where new answers generate novel questions that may be answerable by clinical trials or by alternate research designs. Consequently, this third epoch in research on research is witnessing an expansion of the standards for evaluating research design to incorporate observational studies (ie, CONSOB) and experimental designs (ie, CONSER). In the same vein, it is now evident that the concept of the NNT, which strictly applies to clinical trials and refers to computing the number of patients needed to obtain the desired outcome or to prevent unwanted side-effects in the dental practice, must be expanded. When a clinician wishes to assess the best available evidence about compound X as a treatment for oral cancer and consults the entire body of literature, the situation may occur that several studies report animal survival rates following administration of compound X. Should the clinician be so blind as to ignore these reports, or could important information be obtained from these reports, which might be beneficial to the patients?
There is now general agreement on the latter. Therefore, the need is emerging to expand the concept of NNT. It is proposed that the present conceptualization of NNT clinical trial (NNTcl) be broadened for applications to animal studies (ie, NNTan), and to tackle research that examines the survival of cells in culture in in vitro studies (ie, NNTiv). A third important line of refinement of evidence-based research in this current evolutionary epoch recognizes that the research on research seeks to establish some degree of quality control on the published research literature with the aim of helping and assisting the dentist in the decision-making process for clinical practice. The quantification provided by the Timmer and the WWH scales currently in use permit analysis by means of the acceptance sampling. This technique is similar to the statistical approach designed to decide whether or not to accept a given lot of a manufactured product. That is to say, the process of examining the evidence generated from an identified set of published reports is evaluated for acceptability. The acceptance sampling analysis generates information on the basis of the attributes (ie, nominal variable: reliable vs unreliable research article) or of the characteristics of the identified information (ie, continuous variable assessed along an interval scale, that is, the individual scores produced by the Timmer and the WWH scales). The interpretation of acceptable sampling analysis pertains to evidence-based research, in that it formalizes the process of quality control research, and serves to assess, to quantify, and to analyze the quality of published research in dental practice. It generates summative descriptive data (ie, means, standard deviation) about the relative strengths and weaknesses in the studies’ methodology, design, and data analysis. Therefore, it provides information to the clinician about what specific domain in any given research article, and in the overall domain of the systematic review or best-case study, is particularly weak or strong. Lastly, it provides critical information to the researcher for planning better and more productive research in that area.12

CONCLUSION: THE FUTURE OF EVIDENCE-BASED RESEARCH IN DENTAL PRACTICE: THE FOURTH EPOCH

Critical trends point to the future in evidence-based dental practice. In brief, they fall into 4 principal practical domains: 1) As the process of research on research is rigorously established and reliable readers increasingly generate best-case studies and systematic reviews in specific domains of dental practice, the consensus statements must be communicated to the clinician for use in decision making. A process to fill this specific need has been formalized and is now available on the web for consultation (eg, askward.net) by dentists in clinical practice. 2) Systematic and rigorous training in research on research in dental practice has been developed and is provided to pre-dental students, dental students, graduate students, and residents to help establish tomorrow’s generation of dentists fully capable of producing best-case studies and systematic reviews for themselves, and of critically evaluating evidence-based research and consensus statements generated by others. Continuing education courses in the context of dental schools and of local and national dental associations have been developed to update dentists currently engaged in their successful dental practice. 3) Evidence-based research is espoused to decision-making theory to ensure that clinical decision making in dental practice fully rests on the best available research evidence for the ultimate benefit of each individual patient. 4) Taken together, these concepts are increasingly taken into consideration in the political arena that drives funds available for research (ie, Congress appropriation to the National Institute for Dental and Craniofacial Research) and the domain of insurance recommendations, which increasingly rests on consensus statements of the best available evidence to determine what treatment can or cannot be claimed for coverage.

REFERENCES
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APPENDIX 1
Jadad’s Scale
(CONSORT)
1. Randomization – trials that report that the trial was a “randomized” one are to receive a point. Trials that describe the method of randomization, such as a table of random numbers, computer generated, receive an additional point. However, if the report described the trial as a randomized, and it was inappropriate, such as date of birth or hospital numbers, a point is deducted.
2. Double-blinding – trials that report that a trial was “double-blinded” are to receive a point. Trials that describe the method of double-blinding, such as identical placebo, active placebo, receive an additional point. However, if the report described the trial as double-blinded and it was inappropriate, such as comparison of tablets versus injection with no double dummy, a point is deducted.
3. Withdrawals and drop-outs – Trials that report the number and reasons for dropouts and withdrawals in each group are to receive a point. However, if there is no statement on withdrawals, this item must be given no point.
Total score goes from 0 to 5.
0-2 poor quality
3-5 high quality

APPENDIX 2
Fresno Scale adapted for dentistry
The practice of Evidence-Based Medicine/Dentistry(EBM/D) involves some basic knowledge and skills related to searching and evaluating medical literature. This instrument was developed as a UCSF-Fresno Medical Education tool designed to assess the level at which one is already using EBM skills. It was adapted for dentistry.

Please complete the entire test in one 30-min sitting. There are 7 short answer questions, 2 questions that require a series of mathematical calculations, and 3 fill-in-the-blank questions.

Answer questions 1-4 based on the following clinical scenarios:

- You have just seen Lydia who recently had a periodontal procedure. She plans to begin aggressive oral hygiene, but also wants to start antibiotics. You generally prefer to prescribe combination oral antibiotics, but you fear that these might interfere with some of the pain medication Lydia is taking for fibromyalgia.
- John is an 11-year-old boy who presents with chronic low-grade toothache. He has grown frustrated with the inconvenience of his problem. You have excluded the possibility of pulpitis and a cracked tooth as possible causes. You consider recommending an alternative diagnostic plan for pulpitis, but a colleague tells you he thinks it would be “worthless” and suggests that you treat with VIOXX.

1. Write a focused clinical question for each of these patient encounters that will help you organize a search of the clinical literature for an answer and choose the best article from among those you find.
2. Where might clinicians go to find an answer to questions like these? Name as many possible types or categories of information sources as you can. You may feel that some are better than others, but discuss as many as you can to demonstrate your awareness of the strengths and weaknesses of common information sources in clinical practice. Describe the most important advantages and disadvantages for each type of information source you list.
3. Choose to focus on one of the clinical scenarios (periodontal procedure, chronic pain). What type of study (study design) would best be able to address this question? Why?
4. If you were to search Medline for original research on one of these questions, describe what your search strategy would be. Be as specific as you can about which topics and search categories (fields) you would search. Explain your rationale for taking this approach. Describe how you might limit your search if necessary and explain your reasoning.
5. When you find a report of original research on these questions, what characteristics of the study will you consider to determine if it is relevant? Include examples.
6. When you find a report of original research on these questions, what characteristics of the study will you consider to determine if its findings are valid?
Include examples (You’ve already addressed relevance, and question 7 will ask how to determine the importance of the findings… for this question, focus on the validity of the study.

7. When you find a report of original research on these questions, what characteristics of the findings will you consider to determine their magnitude and significance? Include examples. (You’ve already addressed relevance and validity… for this question, focus on how to determine the size and meaning of an effect reported in the study.)

8. A recent study of the diagnostic accuracy of oral carcinoma in diagnosis of expression of gene X included 212 patients with suspected gene X, 49 of whom were subsequently determined to have gene X. Of those with gene X, 41 had abnormal salivation. Of the 163 patients determined not to have gene X, 118 had abnormal salivation.

- Based on these results, the sensitivity of salivation for gene X is
- Based on these results, the specificity of salivation for gene X is
- Based on these results, the positive predictive value of salivation for gene X is
- Based on these results, the negative predictive value of salivation for gene X is

9. A recent randomized trial found that 29% of diabetics with periodontal disease and associate cardiovascular disease treated with pravastatin suffered a recurrent coronary event during 5 years of follow-up, whereas 37% of the placebo group suffered recurrent coronary events.

- The absolute risk reduction for recurrent events is
- The relative risk reduction for recurrent events is
- The number needed to treat (NNT) to prevent one recurrent event is

10. The recent HERS study compared women on estrogen supplements to women on placebo. Results revealed a relative risk of osteoporosis was 2.89 for the women on estrogen. This suggests that estrogen treatment poses a coronary risk, but we wonder if this difference is statistically significant, so we look at the confidence interval. Give an example of a confidence interval that would support the conclusion that the rate of osteoporosis was indeed (statistically) different for these 2 treatment groups.

11. Which study design is best for a study about diagnosis?

12. Which study design is best for a study about prognosis?

APPENDIX 3
Evidence Based Dentistry Worksheet
Search the article proactively to find answers to 3 questions posed 3 times and evaluate, on the basis of your own judgment, whether or not the article will be useful to you and to the profession.

1. What
A. What is the Outcome, and is the stated Outcome tested and measured correctly?
B. What are the Findings, how are they presented, and do the Findings respond to the stated Outcome?
C. What is the clinical Significance of the findings, and what is their statistical Significance? Do the findings mean anything anyway? Research-wise? Clinic-wise?

2. Who
A. What was the Sample tested, is the Sample representative of the population under study, of your patients?
B. Are numbers presented in the article that you can trust, and that would permit you to compute the Number Needed to Treat (NNT)?
C. Can the information provided in the article be of any use directly to any patient or group of patients in your practice now?

3. How
A. How was the question addressed from the perspective of design, was it an experiment, an observation, a randomized blind trial; and were the appropriate caveats discussed?
B. How was the Outcome measured, and were issues of reliability and validity presented?
C. How were the data presented and analyzed, was the article dealing with categorical or with continuous data, was it a comparison or a prediction, and were there more than 2 groups and the t-test was used but shouldn’t have been?