Evidence-Based Dentistry. How to design a research? A literature review

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ABSTRACT
Evidence-Based Dentistry forms an important asset in order to make clinical decisions, to practice modern dentistry and to educate dental care professionals. The basis of evidence-based healthcare and health technology assessment is the critical appraisal of evidence supporting a finding. The pyramid of evidence includes several types of studies used to evaluate treatment effects, starting from case reports, observational studies, and randomized controlled trials, the tip of which are systematic reviews, which constitute the highest level of evidence because they attempt to collect, combine, and report the best available evidence using systematic, transparent, and reproducible methodology. The aim is to provide a balanced mix of science and clinical expertise in order to optimize patient care. The translation of research into practice entails the availability of clinically relevant evidence. Although huge sums are invested in dental research, the dental research community has paid relatively little attention to clinical aspects of care.

Introduction
The term “Scientific Medicine” was coined in the year 1990 by Dr Gordon Guyatt to describe a novel method of bedside teaching in medical education (1). Due to lack of enthusiasm for this term Dr Guyatt improvised a new terminology and called it as “Evidence-Based Medicine” (EBM). A year later 1991 the EBM term appeared for the first time in an editorial of the ACP Journal Club (2,3). Currently integration of the best evidence with patient preferences and clinical observation is considered as a standard norm in treatment decisions.

The terminology was later redefined by several other authors (3,4).

In the year 1999, the American Dental Association (ADA) approved the new term evidence-based dentistry (EBD) in clinical dental practice (5,6). EBD is supposed to improve the operator’s skills and knowledge, as well as advance the communication between patients and their dentists about the rationale behind clinical recommendations (7). Evidence is based on the existence of at least one well-conducted randomized controlled trial (RCT) (8). To provide best dental care a sound educational base and good source of current best evidence practice is mandatory (9). Therefore to be a successful dental practitioner it is crucial to implement evidence from research into clinical practice (10,11).

Goals of evidence-based dentistry
A five-phase approach forms the basics of EBD. This involves framing an answerable question from a clinical problem, searching for the best evidence, reviewing and critically appraising the evidence and applying this information in a way to help the clinical practice (12,13). Each evidence has to be assessed according to its merits/demerits and the “best” evidence needs to be implemented (14).

Current status of clinically relevant evidence in dentistry
The dental research community has paid relatively diminutive attention to clinical aspects of care which replicated negatively on the translation of research into practice (15). Outcome studies are sparse for disease-based management of dental caries, periodontal diseases, or facial pain (16,17,18).
The hierarchy of evidence-based practice includes the systematic reviews, which constitute the highest level of evidence. This hierarchy of evidence has been essential in translating the accessible evidence into clinical practice (19, 20). Meta-analysis is also an established method for summarizing the results of numerous randomized trials. The synthesis of the evidence for/against the use of a drug/material can range from good to fair (21,22,23). Systematic review usually emphasizes on a specific clinical question and conducts a wide-ranging literature search to recognize studies with sound methodology. The studies are revised, assessed, and the results concised according to pre-determined criteria of the review question. Meta-Analysis refines the systematic review further by merging all the results using an accepted statistical methodology (24,25,26,27,28,29). The type of research question is important and can help lead the researcher to the best study strategy. To limit search to a specific study design, we can use the database’s filters/limits or add keywords to our search (30,31,32,33,34,35). The types of research designs can be classified as descriptive or analytic and by whether the analytic studies are experimental or observational. Exploratory studies used when the state of knowledge about the phenomenon is poor: small scale, of limited duration, their aim is to explore an unknown field.

Descriptive studies (often surveys) also known as statistical research, describe data and characteristics about the population or phenomenon being studied. However, it does not answer questions. For example, how/when/why the characteristics occurred, which is done under analytic research. Although the data description is factual, accurate and systematic, the research cannot describe what caused a situation. Thus, descriptive research cannot be used to create a causal relationship where one variable affects another (35,36). On the other hand analytical studies are used to test hypotheses: small/large scale. Examples: case-control, cross-sectional, cohort Case Series Clinical case-series: usually a coherent and consecutive set of cases of a disease (or similar problem) which derive from the practice of one or more health care professionals or health care settings. Clinical case-series are of value in epidemiology for a wide range of purposes: studying predictive symptoms, signs and tests of diseases, creating case definitions, conducting clinical education, audit and research. Research in Health services, establishing safety profiles, diagnosis (case definition) or, for mortality, the cause of death, for determining the date when the disease or death occurred, describing the place where the person lived, worked, for describing the characteristics of the population. It also provides the opportunity to collect additional data from medical records (possibly by electronic data linkage) or the person directly (37, 38, 39). Spotting the study design can generally be worked at by looking at the three following issues which include: What was the aim of the study? If it is an analytic study, was the intervention randomly allocated? The third question regards the timing of the determination of the outcomes (39, 40).

Merits and demerits of the designs

A RCT is an experimental comparison study in which participants are allocated to treatment/intervention or control/placebo groups using a random mechanism (see randomization), best for studying the effect of an intervention. The major advantages of RCT are that it provides an unbiased distribution of confounding factors. It provides more likelihood of blinding. It also provides randomization which facilitates statistical analysis. The major disadvantages are that it is expensive. It also creates chances for volunteer bias and may be ethically problematic at times.

Crossover Design is a controlled trial where each study participant has both therapies. For example, randomized to treatment A first, at the crossover point they then start treatment B. It is only relevant if the outcome is reversible with time (38, 39, 40), the major advantages are that all subjects serve as own controls and error variance is reduced thus reducing sample size needed. All subjects receive treatment (for some time at least). Statistical tests assuming randomization can be used, and blinding can be maintained. The major disadvantages are that all subjects receive placebo or alternative treatment at some point of time. The washout period is lengthy or sometimes unknown. The design cannot be used for treatments with permanent effects (38,39). In a Cohort Study the data are obtained from groups who have been exposed, or not exposed, to the new technology or factor of interest. Example- data obtained from databases, no allocation of exposure is made by the researcher. It is best for study the effect of predictive risk factors on an outcome. The major advantages of this study are that it is ethically safe, the subjects can be matched, and the timing and directionality of events can be established, the eligibility criteria and outcome assessments can be standardized, the study design is administratively easier and cheaper compared to randomised clinical trial. The main disadvantage is that the controls may be difficult to identify, the exposure may be linked to a hidden confounder, blinding is comparatively difficult and randomization is not possible; in case of a rare disease, large sample sizes or long follow-up are necessary (38,39).

Case-Control Studies patients with a certain outcome or disease and an appropriate group of controls without the outcome or disease are selected and then information is obtained on whether the subjects
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have been exposed to the factor under investigation (34,35,36). The main advantages are that the design is swift and inexpensive and the only feasible method for very rare disorders or those with long lag between exposure and outcome. In case control studies fewer subjects needed than cross-sectional studies (34,35). The main disadvantage is reliance on recall or records to determine exposure status.

A Cross-Sectional Survey is a study that examines the relationship between diseases (or other health-related characteristics) and other variables of interest as they exist in a defined population at one time (i.e. exposure and outcomes are both measured at the same time). It is best for quantifying the prevalence of a disease or risk factor, and for quantifying the accuracy of a diagnostic test. The advantages are that the study design is cheap, simple and ethically safe (38, 39). The major disadvantage is that the study design establishes association at most, but not causality (40).

Grading the strength of evidence
Guyatt et al developed an optimal grading system based on the idea that guideline panels should make recommendations to administer or not administer an intervention based on a trade-off between benefits on the one hand and risks, burdens, and potential costs on the other (19). They provide recommendations at two levels, strong and weak. A Grade 1 recommendation (strong) is if guideline panels are very certain that benefits do or do not outweigh the risks and burdens. A Grade 2 (weak) recommendation is if panels think that the benefits and the risks and burdens are finely balanced or applicable and uncertainties exist above the magnitude of the benefits and risks (19, 40).

Discussion
Evidence-based dentistry involves defining a question focused on a patient-related problem and searching for reliable evidence to provide an answer. Once potential evidence has been found, it is necessary to determine whether the information is credible and whether it is useful in one's practice by using the technique of critical appraisal (39, 40). There is a growing need to bridge the gap between research and clinical dental practice and to optimize the information available to clinicians and patients. This need can somewhat be met by formulating evidence-based clinical guidelines for best practices that the dentists can refer to with simple chairside and even patient-friendly versions. Since both dentists and patients are already using online resources, it is of interest that the right kind of resources should be made available to them. It is also critical that these resources must be derived from high-quality evidence-based research, which can be used to establish the best standards for clinical care. The concept of evidence-based medicine was introduced in the 19th century and referred to as the conscientious, explicit, and judicious use of current best evidence in making best decision about the care of individual patients (2, 3).

The same principle has been utilized in dentistry worldwide with some of the top dental organizations such as the American Dental Association (ADA) and the American Academy of Pediatric Dentistry at the forefront of this development. The ADA defines the term “evidence-based dentistry (EBD)” as an approach to oral health care that requires the judicious integration of systematic assessments of clinically relevant scientific evidence, relating the patient’s oral and medical condition and history, with the dentist’s clinical expertise and the patient’s treatment needs and preferences (5). As it is clear, the ADA identifies three main areas in evidence-based dental care: Relevant scientific evidence, patient needs and preference, and dentists’ clinical expertise. Since the patient needs/preferences and clinical expertise are subjective and can vary among various providers and population, relevant scientific evidence is of critical importance. There is perhaps no perfect recipe for optimal clinical practices, but keeping it evidence-based is probably the clinician’s best bet. Among the available hierarchy of evidence, systematic reviews and meta-analyses take the top position and contribute to the highest level of evidence, followed by randomized clinical trials (RCTs). These are followed by non-RCTs, cohort studies, case–control studies, cross-over studies, cross-sectional studies, case studies, and expert opinions (40, 42).

Even though we may have the best evidence attained from well-done systematic reviews and meta-analyses in certain areas of dentistry, it is often monotonous for the practitioner to read through the elaborate reviews and extract relevant information out of them. For this purpose, it is of principal importance to create clinical recommendations/guidelines and critical summaries that can be useful to all (40, 41). The success of current efforts towards evidence-based health services in many countries depends on well-organized transfer of research findings to health practitioners. However, there is a delay in research being adopted. In part this is due to difficulties in understanding or oversimplifying research findings, in part to inactivity, organisational structures and information. Clinical guidelines are usually cited as being the most effective product of evidence assessment and means of getting research into practice. The processes by which they are prepared and disseminated are discussed.

Current clinical practice necessitates that health professionals adapt to changing systems and adopt new techniques. Therefore, in future, practice research to assess clinical interventions and
dissemination and execution strategies will become increasingly important. Recognised blocks to such research include lack of interest, lack of involvement, lack of time and lack of financial compensation. High-quality research in dental primary care necessitates academics and dental service providers working in partnership on topics that are relevant both to clinicians and policy makers. Good project administration, education and training are essential (41-43). Simultaneously, it is important to identify that there are several barriers to the implementation of EBD. The information overflow from so many websites and journals can often overpower a clinician. Sometimes, due to the lack of data, the systematic reviews may be insufficient to produce relevant clinical guidelines (43). Another barrier could be related to patient needs and preferences, which may cause everything else to take a backseat. To conclude, the clinician’s experience and lack of enthusiasm to change what may have worked well for the practice for years can signify a challenge (43).

Obstacles to evidence-based clinical practice implementation

The use of evidence-based practice (EBP) in oral health care has been assigned as an important concern in different countries. However, the implementation of EBP to increase the effectiveness of dental care seems to face many obstacles (44). There exist potential barriers to change, primarily environmental, as there are restrictions of time and organisation of the practice. Secondarily in education, due to inappropriate continuing education and failure to join with programs to endorse better quality of life. There is non-existence of enticements to participate in effective educational activities. The third factor is the lack in health-care of financial resources and defined practice populations, Unsuccessful or unproved activities promoted by health policies, failure to provide practitioners with access to appropriate information. In society the influence of the media on patients in creating demands or beliefs (44) should not be neglected.

A qualitative study was carried out to evaluate the obstacles among the Belgian, Dutch-speaking dentists experience in the implementation of EBP in routine clinical work. Three major groups of obstacles were identified which relate to difficulties in evidence, partners in health care and field of dentistry. Their findings recommended that educators should provide communication skills to aid decision making, address the technical dimensions of dentistry, promote lifelong learning, and close the gap between academics and general practitioners in order to create common understanding (48-50). The most common barriers to implementation of early-adopting dentists is the strain in changing current practice model, confrontation and condemnation from colleagues, and absence of trust in evidence or research (47-51).

The use of evidence-based dentistry delivers an answer to these problems for the dentist. The use of an evidence-based approach can assuredly help clinicians who want to stay well-informed of changes in their areas of health-care by following them with the assortment of relevant articles and will aid them to efficiently extract and apply the information (52). Electronic medical databases, such as Medline, Pub Med and The Cochrane Collaboration, have made easier both the distribution and the access to information (53). Currently, other strategies available to help the dentist keep abreast with the current information are (52) such as professional journals available on-line, professional and university continuing education meetings (which should give the possibility to interact with the author of a new evidence), study clubs composed by colleagues. It is generally accepted that systematic reviews and randomized controlled trials represent the best levels of evidence, whereas case reports and expert opinions are the lowest; about diagnosis, prediction or causation, cohort studies or case control studies are surely more appropriate, remaining clearly defined in any of these study inclusion and exclusion criteria adopted (53-55).

Conducting of research

Planning a good research project is the primary basis of significant publications. Fundamental stipulations for a good research include focusing on an area of interest. Accidental choice of research projects dilutes the resource contribution in random directions and results in lack of identity of the person or faculty. Generating research hypothesis must aim at answering clinically relevant questions. The rationale for the choice of an option could also result in a new concept of thinking (56).

Role of study designs

Both in vitro and clinical study designs for various questions rising from clinical practice or knowledge can be solved by applying various sections of the interactive loop. Depending on the research question, the structure of each study design facilitates the origin of appropriate answers. Preceding to section of the study design, there must be a valid research question. The genesis of a research question should primarily emphasise on answering several aspects of a broader research interest. The prime effort in research is not to focus on the research question, but to focus on your research awareness, on study designs and their relevance in answering explicit research questions (57).
Role of biostatistics

The role of biostatistics is often unnoticed and overlooked in the current research work in our specialty. Biological systems form a complex network and variation between the units forming the biological systems is the norm. On account of this inconsistency within the systems, it is often difficult to distinguish between groups within the system. The science of biostatistics helps us to quantify and evaluate its inconsistency within and between groups that make up the biological systems. Statistics is not absolute value it is rather a measure of the measure of the probabilities of occurrence of an event (57). Biostatistics is less of mathematics and more of a method of determining the relevance of the research findings by application of statistical methods. This retains equal importance in both in vitro as well as clinical research, because this statistical inference lays a foundation for the evidence deduced from any study. Hence the role of the statistician and the clinical researcher are equivalent in finding answers to any research question. Understanding biostatistics is important in dental research methodology (57, 58).

About dentistry, many procedures, as in the case of dental implants, have been introduced without randomized controlled trials, as many studies are based on many clinical cases and long-term follow-up. (59). This is mainly since such studies are expensive, difficult to blind, and often require specific inclusion criteria, or present ethical issues (60). A hierarchical analysis of the literature may help clinicians to make decisions about the care of individual patients based on the best available evidence. This is evidence-based dentistry and it requires that practitioners’ question and think about what they are doing, keep abreast of new techniques and developments. This means that time must be spent searching and assessing the literature, and information from any source should be questioned to determine its validity (61). By formulating a clinical question, carrying out an efficient literature search, evaluating the literature, and when appropriate, applying it to patient care, dentists can provide quality care in a quickly changing environment. Additional benefits are that it makes it easier to justify treatment decisions, especially when there is a complaint or a dento-legal issue (58, 59, 60, 61).

The practice of evidence-based medicine is a process of lifelong, self-directed, problem-based learning which leads to the need for clinically important information about diagnosis, prognosis, therapy and other clinical and health care issues (61, 62, 65). Recent years have seen an increase in the importance of evidence-based dentistry, aiming to diminish to the maximum the gap between clinical research and real-world dental practice. Aim of evidence-based practice is the systematic literature review, which produces the best evidences and offers the basis for clinical practice guidelines (66, 67, 68, 69).

Conclusion

The advancement of outcomes of research with the consequent accumulation of scientific evidence and the implementation of evidence-based practice is likely to improve the delivery of a high standard of quality dental care in the coming years. The requirement for good research is to find the best evidence for clinical practice, for specific problems, and to address methods in reducing the burden of illness on a larger scale.

References


