Introduction

The movement toward incorporating evidence-based decision making in dental practice is exciting and enriching. It is also challenging. For example, with a given clinical question, what is the clinician to do when there exists only flawed evidence or no evidence at all? Does the clinician have in place an overriding context, an “operating system” from which he or she will advise and treat patients? To address these important issues, this article introduces the Precautionary Context Clinical Practice Model and it provides examples of its application and relationship with the evidence-based approach. Although many of the examples used here are periodontal, the concept is applicable to all aspects of dental clinical practice. A discussion regarding evidence-based learning group rationale, development, and facilitation follows.

The Evidence-Based Approach

Evidence-based practice has been defined as combining best research evidence along with clinical experience and patient preferences to improve treatment outcomes. However, a large amount of published scientific research provides inaccurate information that significantly impairs the clinician’s ability to use these resources as high-level evidence when advising patients and providing treatment.

Fletcher and Sackett are credited with originating the concept of “levels of evidence” to rank the validity of research evidence and then correlate these levels to grades of recommendations. These evidence levels have evolved over the years. Using the levels of evidence developed by the Centre for Evidence-Based Medicine at Oxford University, CEBM (http://www.cebm.net/levels_of_evidence.asp), The Journal of Evidence-Based Dental Practice (JEBDP) has created a useful modified grading system, a portion of which is depicted in Table 1. The levels (grades) give the reader a better understanding of the quality and strength of the study. The grades are based on the study’s ability to control for bias and to demonstrate cause and effect. Although each level of evidence contributes to our body of knowledge, it behooves the clinician to always use the best available evidence for each clinical question. For example, not all clinical questions can be answered by the gold standard (level 1a) of evidence: the systematic review of high-quality randomized controlled trials. Implementing the evidence-based approach in dental clinical practice is not without its challenges.

The Precautionary Context Clinical Practice Model

The “Precautionary Context Clinical Practice Model (PCCPM)” is introduced here to provide the clinician a description of the domain within which they can
utilize the best scientific evidence, apply clinical experience and judgment, and serve patient preferences/values in order to provide clinically relevant outcomes. This novel Clinical Practice Model is depicted in Diagram A.

The Precautionary Context is not new. In medicine it can be traced back to the phrase “First Do No Harm” originated by Hippocrates in his work, Of the Epidemics, Book I, Section XI (400 BCE). The essence of the guiding ideology of the Precautionary Context is captured in commonsense aphorisms such as “Better safe than sorry,” “An ounce of prevention is worth a pound of cure,” and “Look before you leap.”

The core guiding principles of the Precautionary Context are the following:
- Ask always, “How little harm is possible?”
- Deliver treatment that provides the highest degree of safety, effectiveness, and long-term value.

The Precautionary Context shares its core philosophy of minimizing the risk of harm with a governmental regulatory framework, the Precautionary Principle (PP). However, as it is instituted on the government and large agency level, the PP is not readily applicable to dental clinical practice on the local level.

Emerging in European environmental policies in the late 1970’s, the PP has been enshrined in numerous international treaties and declarations. It is, by the Treaty on European Union (1992), the basis for European environmental law and plays an increasing role in developing environmental health policies as well.

The PP recognizes that the absence of full scientific certainty shall not be used as a reason for postponing decisions where there is a risk of serious or irreversible harm. Utilizing the PP, the government of Canada developed a framework which outlines the guiding principles for the application of precaution to science-based decision making in areas of federal regulatory activity for the protection of health and safety and the environment and the conservation of natural resources.

The Precautionary Context and the Precautionary Principle are distinctive within science-based risk management. Making choices based on least harmful alternatives challenges conventional risk management assumptions. These are often guided by entirely different principles perhaps best reflected in the aphorism, “Nothing ventured, nothing gained.”

Adopting the PCCPM allows the opportunity to improve the way decisions are made. Using this approach instead of asking, “How much risk will be allowed?” a very different question is asked: “How little harm is possible?”

Although dental care can never be completely risk-free, a risk that is unnecessary, and not freely chosen, is never acceptable. Adopting the Precautionary Context for clinical decision-making facilitates the integration of varied and potentially conflicting factors such as patient preferences, economic limitations, clinician experience and scientific evidence in order to recommend safe and effective treatment options for the patient.

The PCCPM provides a domain within which clinical decision making is based on the best scientific evidence—science that is explicit about what is known, what is not known, and what may never be known about potential hazards. The goal of the Precautionary Context is to prevent harm, not to prevent progress. Applying the Precautionary Context approach fosters innovation in producing better materials, safer products, and alternative dental care delivery processes. The goal of the PCCPM is to enhance the clinician’s stewardship of patient care.

Unfortunately in today’s regulatory system, in the United States lack of proof of harm is usually misinterpreted as proof of safety. While this approach has been successful in approving drugs that may help manage many problems, it has also been less effective in identifying long-term side effects, toxic properties and/or disease transmission risks for many therapeutic agents. Adopting the PCCPM better enables the clinician to take action despite scientific uncertainty about
the magnitude of risk of harm. This new framework removes excuses for inaction on the grounds of scientific uncertainty (‘paralysis by analysis’).

Clinical Practice: The Evolution of the PCCPM and the Incorporation of the Evidence-Based Approach

In 1981, my patient care philosophy was to “passionately provide excellence in therapy with exceptional patient service and care.” Although satisfied that these objectives were achieved, there was a desire to provide even better service by sharply focusing in on the clinical practice model (what kinds of treatments we provided and the outcomes patients received). In 1994, our practice put in motion a distinctive clinical care outcomes model based on the guiding principles of “deliver treatment that provides the highest degree of safety, effectiveness, long-term value, and patient comfort” and “Ask always, ‘How little harm is possible?’” Risks, benefits and alternative therapeutic approaches were also discussed in the light of patient preferences and circumstances.

The Precautionary Context concept evolved from these guidelines and has been serving as our Clinical Practice Model on a daily basis (Diagram A).

This clarity of resolve to implement our goals was both exhilarating and demanding, as it necessitated rethinking and revisiting some of the literature that guided decision-making, but now from the Precautionary Context Clinical Practice Model perspective. The revised questions from which answers were sought always contained a component of asking: how little harm is possible and which treatments provide the highest degree of safety, effectiveness, and long-term value based on the quality of evidence available?
At that time, it became evident that literature reviews, specialty position papers, and the publishing criteria of the vast majority of journals left much to be desired with respect to the objectives to base clinical therapeutic decision making upon strong scientific evidence as well as keeping it within the PCCPM. Sifting through the volume of research publications proved to be fairly difficult and time consuming.

However, the situation markedly improved in dentistry toward the end of the last century with the recognition of the Evidence-based Approach. In 1998 and 2001 respectively, the *Journal of Evidence Based Dentistry* and the *Journal of Evidence-Based Dental Practice* began publication. Since then, use of the *JEBD, JEBDP, PubMed*, and the Cochrane Collaboration Oral Health Group Reviews and Protocols have significantly contributed to the ability to have sound scientific footing for the PCCPM (Diagram A) used in my private practice, research, and teaching.

Examples of Clinical Care Changes Resulting From the Absence of Evidence

As a result of reviewing the scientific literature as well as product and procedure information, it became clear that the old admonition, “the absence of evidence is not evidence of absence” would become an important clinical decision-making tool. There was a lack of reasonably strong scientific evidence to support the continuation of certain procedures and protocols that exposed our patients to unnecessary risks when assessed within the PCCPM. The examples provided demonstrate clinical outcomes that can be achieved by adopting the PCCPM for clinical decision-making when there is an absence of evidence.

Using sterile water during dental surgery. It has been clearly demonstrated that the risk of disease transmission increases during surgical procedures with the use of nonsterile output irrigant/coolant.7-13 Also, owing to the presence of biofilm, the use of conventional dental unit waterlines (with or without filters) for surgical procedures increases the risk of disease...
transmission. In 1993, the Centers for Disease Control and Prevention (CDC) advised that “sterile saline or sterile water should be used as a coolant/irrigant when surgical procedures involved the cutting of bone are preformed.”

In 1995 there was no California or federal regulation enacted to enforce the CDC recommendation. Additionally, there was an absence of evidence to establish a cause-and-effect relationship in dental surgery. However, making decisions within the domain of the Precautionary Context Clinical Practice Model (PCCPM) enabled us to take action despite scientific uncertainty about the magnitude of risk of harm. As a result, since 1995, all traditional dental unit waterlines were eliminated from our practice; only USP sterile saline has been used for output surgical irrigant/coolant; and sterile irrigant/coolant has been delivered during all surgical procedures via detachable irrigation tubing sterilized for each procedure or by sterile irrigation syringes.

In 2003, using an evidence-based approach to establish its updated Infection Control Guidelines, CDC recommended the following: “use sterile saline or sterile water as a coolant/irrigant when performing oral surgical procedures. Use devices specifically designed for delivering sterile irrigating fluids.” The level of evidence cited was Grade 1B: “strongly recommended for implementation and supported by experimental, clinical, or epidemiologic studies and a strong theoretical rationale.”

Following this CDC recommendation and effective April, 2005, the Dental Board of California updated the Infection Control Regulations of the Dental Practice Act (Section 1005, Section C 15: Irrigation) mandating that “sterile coolants/irrigants shall be used for surgical procedures involving soft tissue or bone. Sterile coolant/irrigants are deemed to be sterile when delivered using a device or process that has a Federal Drug Administration (FDA) marketing clearance for delivery of sterile coolant/irrigants to the patient. Delivery of sterile coolant/irrigants shall be in accordance with the manufacturer’s directions.”

Using the Precautionary Context Clinical Practice Model enabled our practice to take action and decrease the risks of harm for our patients 10 years before mandated regulations went into effect.

Utilizing human cadaver and animal tissue grafts in dental surgery: are they safe and effective, providing patients long term value? In this example, the flexibility and adaptability of the PCCPM are illustrated. Raising and examining this question within the PCCPM context, allows for two entirely different conclusions to be drawn. While strong scientific evidence has not demonstrated that cadaver and animal tissue graft material are the safest, most effective and best long-term value approach in elective dental surgery, neither has it determined that there exists a proven cause-effect relationship routinely implicating these materials in disease transmission and patient morbidity. However, although approved by the Food and Drug Administration (FDA), these grafting materials do carry warnings, as they are not guaranteed risk-free from transmitting diseases to patients. Further, the best scientific evidence has not established that these materials provide significantly improved clinically relevant outcomes with respect to therapeutic effectiveness or improving tooth longevity/long-term value.

Although there are reported cases of disease transmission from the use of allograft materials in medical procedures, to date there is no published substantive evidence of disease transmission from the use in dental procedures. High quality evidence demonstrates allograft usefulness in clinical practice.

By adopting the PCCPM, clinicians may choose either to use or not use these materials; both choices have reasonable scientific support. Within the PCCPM, because of the absence of strong evidence, the decisions will be weighted more towards individual clinician philosophy and preference as well as responsible patient stewardship by way of thorough and balanced education of the risks and benefits in order to foster a greater ability within each patient to make appropriate choices for themselves.

As a result of evaluating the risks and benefits of these materials, in 1994, I chose to eliminate the use of all human cadaver and animal tissue graft materials from our treatment protocols. In the absence of evidence, refocusing clinical decision-making on reducing harm was a key factor in the adoption and elimination of certain clinical procedures and protocols (Table 2).

When the scientific evidence (or lack thereof) is assessed within the PCCPM, it allows the clinician the opportunity to improve the way decisions are made (Diagram B). The strongest as well as the weakest evidence is critically assessed within a tangible framework. This helps simplify the decision-making process, enabling the clinician to choose the best available evidence based upon which procedure(s) satisfy the criteria of the Precautionary Context guidelines:

- How little harm is possible?
- Deliver treatment that provides the highest degree of safety, effectiveness, and long-term value.

Educating our patients about the Precautionary Context places demands upon our communication skills and time, but ultimately it is very rewarding. Contrary to what one might assume, using the PCCPM has
not reduced the number of overall clinical procedures provided by our practice; it actually increased the practice care scope and procedure delivery.

Examples of Clinical Care Changes Resulting From the Presence of Evidence

JEBDP, JEBD, PubMed, and the Cochrane Collaboration Oral Health Group Reviews and Protocols provided sound scientific footing for the PCCPM used in many settings including private practice and teaching. Table 3 outlines some of the positive changes adopted based on sound scientific evidence.

The clinical care changes adopted in my practice have resulted in improved patient outcomes as defined by the PCCPM. It is important to note that all practice employees participated in the process of adopting the model. This created a shared vision and dental team empowerment through knowledge, thus enabling greater employee satisfaction.

Continuing Education: Interactive Learning Groups for Evidence-Based Knowledge Sharing

With respect to evidence-based teaching, Elliot Abt, DDS, MS, points out in his excellent article, “Complexities of an Evidence-Based Clinical Practice”: “From the literature, it has been shown that the standard continuing education lecture is rather ineffective at changing practitioner behavior. Nor does passive dissemination of research findings or guidelines effectuate changes in the way clinicians practice.”39 The article further
points out that smaller interactive group work with the teachers serving as facilitators of knowledge transfer is more likely to change practitioner behavior.

I too believe that teaching evidence-based skills for application in clinical practice is more readily advanced by way of small group formats. Over the past 15 years, I have decreased providing traditional continuing education lectures and have emphasized a teaching format that is mostly focused in small group interactive knowledge sharing (learning groups). Additionally, I have significantly reduced passive dissemination of educational materials to colleagues.

The following is a summary outline of the process I use to develop and facilitate interactive learning groups for evidence-based knowledge sharing.

Because JEBDP provides clinicians extraordinary exposure to a diverse array of topics in medicine and dentistry that affect patient care every day, it is recommended to use the journal as the core working reference during learning group sessions.

## Getting Started

1. Select learning group participants. Although optimal group size is a matter of personal preference, a range of 8 to 15 participant dentists seems to work best. Along with a very strong desire to improve patient treatment outcomes, the most important
philosophical common grounds for a successful learning group are the following:

- Belief that strong scientific evidence is a core foundation building block for their practice
- Appreciation and desire for interactive problem-solving
- Acceptance that change is a constant
- Generosity and interest in knowledge sharing
- Commitment to fully participate in and attend the learning group.

2. Invite the prospective members to an organizational and planning meeting.

3. In advance of the meeting, provide the attendees with a written overview of evidence-based dental practice and reference materials. This allows prospective group members to explore evidence-based concepts and practices on their own before the first session. Although one could write one’s overview for prospective group members, there are a number of excellent published articles that can be used. The following recently published articles admirably meet the task at hand:

- “Complexities of an Evidence-Based Clinical Practice”
- “Online Resources, Courses and Training Programs”

Order one back issue copy of each of the journals in which these articles are published for each prospective group member. It allows for a more productive first meeting if members have already had the opportunity to acquaint themselves with the JEBDP. Alternatively, one should contact JEBDP’s publisher (Elsevier’s Rights dept: Fax 1-215-238-2239) for permission to photocopy the articles.

4. Provide the JEBDP back issues or article copies to the prospective group members and ask them to review the articles in advance and to bring their copies to the organizational meeting.

Group Organizational Meeting. Topics should include the following:

1. Presentation of the purpose and intended outcomes of the learning group.
2. Discuss the advantages of the evidence-based approach in clinical practice with review of the previously provided reference material.
3. Group housekeeping discussion. Issues should include the following:
   - Identify the group facilitator if this has not already been established.
   - Length of sessions and number of sessions should be determined by the group. Four to six 2.5-hour sessions per year are usually appropriate.
   - CE accreditation: For optimum value to the group members, it is best to provide CE units for the participants. Check with your state board and/or the Academy of General Dentistry for CE provider requirements and licenses. CE accreditation application and ongoing administrative tasks should be shared by the group.
   - Learning group annual dues/fees should be high enough to make participant attendance a priority. Per study group common practice, open a separate bank account with co-signing authority and determine the group treasurer and co-treasurer.
   - Individual subscriptions to the JEBDP are essential for learning group members because the journals are used at each session. It is also advised to have access to all back issues.
   - Recommendation to attend the next International Conference on Evidence-Based Dentistry and Evidence-Based Dentistry Workshop and/or other upcoming evidence-based conferences.
   - The facilitator should create the group contact list and distribute it to each member.
4. Review the format for subsequent learning group sessions. Members should bring their current issue(s) of JEBDP to each session. It is best to have consistent structure (ritual) for each session:
   - Part 1: JEBDP article reviews (as determined at the previous session).
   - Part 2: Further article discussion as needed.
   - Part 3: Review of the most recent issue of JEBDP. Decide on which articles to review during the next session and who will lead each article review (see section 5 below).
5. Review the most recent JEBDP including table of contents and all section heads.
   - Agree upon which articles in this issue the learning group will review during the next session.
   - Article reviews are led by individual members. These reviews should not be the exclusive domain of the group facilitator.
   - Agree on a time limit for each article review. Each article review should end with a discussion regarding its application to clinical practice. The facilitator should keep the meeting on time.
   - After all scheduled articles have been reviewed, allow enough time at the end of each learning group session for open discussion and, on an as needed basis, to further address the articles reviewed during the session.

In addition to the above suggestions, it is beneficial to emphasize the JEBDP study categories during the
TABLE 4. Key advantages of evidence-based learning groups

- Diverse subject matter versus narrow focus study club
- Minimizes mentor/expert opinion bias
- Eliminates literature review bias
- Fosters an egalitarian learning culture rather than a specialist-driven “learn to refer” study club environment

learning group sessions (therapy/prevention; etiology/harm; prognosis; diagnosis; differential diagnosis/symptom prevalence study; economic and decision analysis).

This organizational framework better enables the learning group participants to categorize and critically review articles published in other journals.

The above format offers a learning group some key advantages over a more typical specialist-directed study club (Table 4).

Conclusion

Evidence-based decision making in dental practice is rewarding and challenging. Although there will always be insufficiencies in the currently available best scientific evidence, this continually evolves over time. The PCCPM provides an overriding domain and system within which the evidence-based approach may be more effectively used in clinical practice.

For the private practice clinician, learning, teaching, and sharing evidence-based skills can be a career-long enrichment process. As developments continue to evolve at the large agency levels, efforts at the local level will more rapidly advance the appropriate implementation of Evidence-Based practice in clinical practice.

About the Author

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