Current Topics in Oral Cancer Research and Oral Cancer Screening

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Early identification and proper evaluation of suspicious oral lesions offers the oral health practitioner the opportunity to positively impact our patients' health. In this presentation, I will review the available adjunctive methods and devices for the evaluation of suspicious oral lesions. I will review the studies that have analyzed the effectiveness of these approaches in a clinical setting. The adjunctive techniques which I will discuss are toluidine blue, tissue fluorescence, tissue reflectance and brush cytology. At the end, I will discuss the role that genomics might play in the future in diagnosing and predicting the clinical behavior of oral cancer.

Toluidine blue: Toluidine blue is a vital stain that binds to nuclear material and preferentially stains tissues with high rates of cellular proliferation. Toluidine blue is an effective adjunctive screening tool for identifying premalignant lesions or oral cancer recurrences in those who have already been diagnosed with oral dysplasia or oral cancer. Gray and colleagues reviewed 14 large studies on toluidine blue and found that sensitivity for detecting oral cancer ranged from 40% to 100%, and the specificity ranged from 31% to 92%.[1] Toluidine blue can be associated with a high false positive and high false negative rate. For example, 50% of oral lichen planus lesions were positive and only 42% of dysplasias stained positively.[2] Therefore, the provider must be careful not to overextend the utility of this tool. Although toluidine blue is highly sensitive as a screening tool, it should not be used to rule out malignancy – a scalpel biopsy remains the standard of care. Toluidine blue has also been proposed as a tool to predict progression of oral dysplasia to cancer. In one study, toluidine blue stained lesions with high-risk histologic features, with staining correlated to patient outcome.[3] There is no evidence to support the use of toluidine blue as an oral cancer screening tool for the general population.

Tissue fluorescence: Certain cellular molecules, especially those within mitochondria and lysosomes, absorb the energy from light of specific wavelength. When these molecules move back to their unexcited state, the absorbed energy is released. This energy is referred to as fluorescence emissions. Porphyrins in erythrocytes also contribute to autofluorescence. Oral cancer cells have different autofluorescence emission relative to normal oral mucosa. Technology, such as VELscope, has been developed to capitalize on this difference in autofluorescence between cancer and normal tissue and to use this approach to detect pathologic lesions in the oral cavity. VELscope emits a high intensity light that is blue. Unaffected mucosa fluoresces green, while areas of dysplasia or cancer are darker and do not fluoresce. Indications for the VELscope, according to the manufacturer, are to assist in identifying suspicious oral lesions that may require a surgical biopsy and also to delineate the lesional margins at the time of resection.

To date, there are no rigorous studies demonstrating that VELscope improves oral cancer diagnosis or improves outcome. While one study of 44 patients reported a sensitivity and specificity of 98% and 100% for identifying oral dysplasia or oral cancer, respectively, and was verified by surgical biopsy, all of these lesions were visible with standard incandescent lighting, and the majority of them were clinically suspicious.[4] At this time, it is unclear whether VELscope is useful in detecting suspicious lesions that are not visible with white light. Similar to toluidine blue, VELscope should not be used to rule out malignancy in visible lesions.

Tissue reflectance: Chemiluminescence, or tissue reflectance, is an adjunctive screening tool that is used to detect cervical premalignant or malignant lesions. Two systems using chemiluminescence developed for the oral cavity are ViziLite® Plus and MicroLux DL. The increased nuclear to cytoplasmic ratio characteristic of squamous cell carcinoma increases light reflectance relative to normal epithelium.

The sensitivity of the chemiluminescence devices for highlighting potentially pathologic lesions is high; however, benign lesions, such as leukoedema and traumatic ulcers, test positive. In the available studies, lesions detected by tissue reflectance were also visible under incandescent lighting.[5-9] Because surgical biopsies were not performed to diagnose all detected lesions in the available studies, actual sensitivity and specificity are difficult to report. It is not clear whether these instruments provide any benefit over conventional oral examination under standard incandescent lighting. Oh and Laskin reported that the use of ViziLite® actually made visualizing lesions more

difficult due to the distracting highlights it created.[8] At best, tissue reflectance technology can be used as an adjunctive screening tool to the conventional oral examination. A scalpel biopsy of suspicious lesions is required.

Brush cytology: The brush biopsy (Oral CDx® from CDx Laboratories) is intended for oral lesions that appear innocuous and would not normally be biopsied by the provider. The brush biopsy is intended to be an adjunct diagnostic tool and not a screening tool. Demonstrating efficacy for the diagnosis of suspicious oral lesions with brush cytology is not easy. The population investigated must have lesions that are not already highly suspicious for malignancy, and all lesions in the population must be subjected to surgical biopsy. The available studies evaluating the brush biopsy are not selective for the target population and include likely or biopsy proven malignant lesions. In most of the available studies, lesions that were reported as negative based on the brush biopsy have not been confirmed by a surgical biopsy. In one study, all lesions had both a brush biopsy and a surgical biopsy. The sensitivity and specificity were 92.3% and 94.3%, respectively.[10] A false negative rate of 7.7% is unacceptably high for an adjunctive diagnostic tool. A further significant drawback of this study is that lesions highly suspicious for malignancy were included. Therefore, the sensitivity might be lower. The current literature does not strongly support adding the brush biopsy to the diagnostic armamentarium.

Genomics: The human genome project, completed in 2002, was to revolutionize surgery and medicine. Scientists predicted that once the entire human genome sequence was known that many cancers, including oral cancer, would be curable. However, our comprehensive understanding of the human genome has not cured cancer. In this lecture, I will attempt to explain why cancer has proven to be more elusive and complex than we expected and why genomics has not led to a cure. I will present the modest headway we have made in predicting cancer behavior with genomics and show how this knowledge has impacted our understanding of the key elements of oral carcinogenesis, including: transformation of normal oral mucosa to cancer, local recurrence following resection, development of second primaries and metastasis to the cervical lymphatics. I will show how state-of-the-art genomics might be used in the future to understand and treat oral cancer.

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The State of the Science of Lasers in Dentistry

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Introduction: In the modern surgical therapy of oral diseases there are beneficial applications of minimally invasive surgical techniques, like the use of the laser light, which is able to cut, coagulate or ablate tissues due to its high power density. In general, LASER is an acronym of Light Amplification by Stimulated Emission of Radiation, which is light with a high power concentrated in a focused area, i.e. the target tissue. There are special characteristics for the laser light. Laser light is coherent, which means that the light is directed in a long distance without divergence, in contrast to the sun or a flashlight. It is collimated, which means that the laser light can be concentrated in the target tissue with the highest level of energy in the focus (spot) as well as monochromatic, which means that it has only 1 wavelength. The main part of the laser unit is the active medium. It is the "brain" of the whole system, where electrons can be activated for the emission of photons.

According to the active medium, lasers can be classified into: a) using solid active mediums (crystals), i.e. Er:YAG, Nd:YAG, Ho:YAG lasers; b) using fluids, i.e. the dye lasers; c) using gases, i.e. CO2, He:Ne, Argon lasers and d) using semiconductors, i.e. diode lasers. Dependent on the used power setting, we distinguish lasers to "soft" lasers using a power setting in mW to W level and to "hard" (surgical) lasers using a power level between W and kW. Moreover, all laser units are classified into 5 groups according to the laser safety level (1, 2, 3A, 3B and 4 safety class) according to laser properties that damage vital tissues irreversibly or not (skin, retina). Most of the lasers used in medical applications belong to the class 3B or 4, and for that reason a laser safety officer is requested when lasers are used.

Laser-tissue interactions: There are specific laser-tissue interactions dependent on physical parameters (power, power density, etc.), tissue consistency and laser wavelength. Most important among optical tissue properties are the reflection, absorption, scattering and transmission of the light which take place during laser irradiation. The laser light emission is higher and completely different in the blood vessels, but not in the connective tissue when the wavelength represents the Nd:YAG (1,064 nm) or the diode lasers (980 nm or 810 nm). These tissue interactions are different when the laser wavelength is 10,600 nm (CO2) or the 2,940 nm (Er:YAG laser).

In a similar way, the CO2 laser or the Er:YAG laser can be absorbed better by the superficial soft tissues, especially from lesions with light colors, and have a reduced absorption from pigmented lesions. In addition, Er:YAG laser light emission is higher in the enamel, dentin, bone or other calcified tissues, and does not have high penetration depth in comparison to other laser systems. Therefore, the Er:YAG laser is used today for cavity preparation, decay or bone removal and not as often for soft tissue procedures. The penetration depth of the Nd:YAG laser is 3 to 4 mm in comparison to the CO2 laser, which has only superficial layer effects at a depth of 0.1 to 0.3 mm.

Laser applications in Dentistry: The characteristic differences in properties of laser wavelengths explain the variable clinical effects of lasers observed in dentistry. When treating oral soft tissue lesions, 2 different techniques can be used: excision or ablation. The laser beam can be used in a focused way in order to excise the tissue. For ablative techniques, tissue is removed with vaporisation layer by layer, without the possibility of a histological examination with biopsy. In the case of tissue removal using a laser system, a special informed consent has to be given to the oral pathologist in order to better explain possible structural changes caused by the laser. Because water content in the surface of most oral tissues is high, use of the CO2 laser may be indicated in most soft tissue surgery cases. This allows a relatively precise incision line with sufficient coagulation properties. Table I shows the indications of different laser wavelengths in dentistry.

Hard tissue Applications/Cavity preparation/ Operative Dentistry: Due to high absorption of the Er:YAG laser by hydroxyapatite, cavity preparations can be performed using the correct settings of the Er:YAG laser. However, only small carious lesions can be treated this way today, and unfortunately, this does not take place on a routine basis.

Endodontics: Bacterial reduction in the pulp and canal has been studied using different laser systems. The rapid development of laser technology will make it possible to apply this technology for various endodontic procedures, including the cleaning and disinfection of the root canal.

Periodontology – Implant Dentistry: Periodontal diseases may be treated in a more simple and effective way. Lasers can be used for calculus removal, de-epithelization and to significantly reduce bacteria in the pocket using different laser systems, as well as photodynamic therapy (PDT) in conjunction with non-surgical and surgical therapy. The potential of this treatment is superior; however, large multicenter studies and randomized controlled clinical trials are necessary to compare this kind of therapy with conventional treatments. Patient acceptance and postop-

erative healing events should also be evaluated.

Surgical removal of gingival overgrowth has been performed using the CO2 laser. Use of the CO2 laser produces a comfortable and easy excision, and drug-induced gingival overgrowth can be excised relatively quickly. Occasionally, use of the high-pulsed CO2 laser or combination scalpel excision with laser coagulation in a defocused mode for ablation is recommended. Peri-implant soft tissue overgrowth can also be excised without complications using the CO2 laser. Implant surface irradiation reduces bacteria and may stimulate tissues for bone regeneration as a potential therapeutic advantage for using lasers in the treatment of peri-implantitis. Osseointegration depends upon the laser settings and the selected wavelength used.

Laser Phototherapy: Biomodulative effects with lasers of low power have additional advantages and potential applications due to increased cellular activity, cell proliferation and collagen synthesis. These effects have indications for bone and periodontal regeneration, in the treatment of postoperative edema and oro-facial pain and for improving wound healing mechanisms without complications. However, the exact explanation as to how these effects are produced requires further clarification in the future.

Oral and Maxillofacial Surgery: For the removal of soft tissue tumors and premalignant lesions, the CO2 laser may be used easily using a non-contact, focused beam in a continuous wave mode. In most cases, a power setting between 2 to 6 watts (depending upon the laser unit) is sufficient for most minor surgical procedures. For larger-sized and malignant tumors of the oral cavity, use of the CO2 laser in an ultra-pulse mode may be more advantageous.

For removal of small soft tissue tumors in the oral cavity, the application of fibre-delivery laser systems, like the diode (810 and 980 nm) or the Nd:YAG laser also can be used. Because of the higher penetration depth of these laser wavelengths, the light direction during surgery has to be under control in order to avoid necrosis or other complications in the surrounding healthy tissues. Such complications can be observed when the laser is applied incorrectly near healthy periodontal tissues.

The laser beam will be in contact with the tissue in order to excise the tumor and to make histological examination possible. Non-contact devices lead only to coagulation of the tumor. This may alter the tissue structure after coagulation of the blood vessels, presenting challenges for the pathologist. The coagulation properties of these devices are excellent, and therefore can be used in the treatment of patients with systemic bleeding disorders. Cases of treated premalignant and malignant lesions should be monitored postoperatively to detect possible recurrence.

Table I: Indications and laser wavelengths in dentistry

Application	Laser system
Cavity preparation	Er:YAG
Endodontics	Nd:YAG, diode, Er:YAG
Calculus removal	Er:YAG, ErCr:YSGG
Epithelial removal	CO2, diode, Nd:YAG, ErYAG
Drug-induced gingival overgrowth	CO2, diode
Peri-implant gingival overgrowth	CO2, diode
Peri-implantitis therapy	CO2, diode, Er:YAG
Soft tissue tumors	CO2, diode, Nd:YAG, Er:YAG
Pre-prosthetic surgery	CO2, diode
Precancerous lesions	CO2, Er:YAG
Bone removal	Er:YAG, Er,Cr:YSGG
Bleeding disorders	Nd:YAG, diode, CO2
Bacterial reduction	PDT, diode
Phototherapy	soft lasers

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An Introduction to Grant Writing: De-Mystifying the Process

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This workshop, an expansion of a session presented at the North American Research Conference in Bethesda, Maryland in 2009,[1] was designed to provide an overview of important components of writing a clear, concise and tailored grant application. Topics discussed included: review criteria of significance, approach, innovation, investigators and environment, as well as grant application components of abstract, specific aims, research questions and/or hypothesis statements including PICO components, background and discussion of theoretical model guiding the research, preliminary studies, biographical sketch, timeline and budget. Activities highlighted some aspects in the grant writing process. Our goals were to enhance participants' understanding of the grant writing process, cultivate a persuasive approach for addressing the essential components of a well-written grant and provide insight into how to embark upon a successful, comprehensive grant development process.

Develop a Track Record: The author of a successful grant application and principal investigator of a grant project must first establish a track record. Experience related to the project and to management of a budget are reasonable expectations for any agency or organization granting funding. The path that we followed is similar and may serve as an example for others.

Develop an area of specialty by focusing on a study topic and acquiring knowledge and experience related to becoming an authority in your area of study. Assure your other work contributes to this goal, for example:

- Volunteer to collaborate with established researchers conducting related studies
- Conduct small scale/pilot studies in the area of interest, and publish or present results at research meetings
- Apply for small grants from your institution, associations, foundations or organizations with similar goals; identify new investigator opportunities
- Seek opportunities to gain experience with research protocols, personnel management, budgeting and accounting procedures
- Choose community involvement and design community-based projects related to your study area and build collaborations or coalitions, versus volunteering for others' priorities. Later, you may want to involve community providers in your grant-funded program
- Present related oral presentations, scientific papers and continuing education programs at professional meetings
- Assure work is directed toward benefitting society rather than solely focusing on advancing the dental hygiene profession

Writing the Successful Grant Application: The most important lesson we learned on the path to successful grant writing was that writing a clear, concise and focused grant application with good science is not enough. The successful application must tell an interesting story, plus:

- Be tailored specifically to the funding agency's mission. Present ideas that are easy for reviewers to understand, including why the study is significant and feasible
- Convince reviewers you have the expertise to conduct the planned study and you have the appropriate environment, equipment, collaborators and budget[2]
- Prepare a reviewer-friendly application that is well organized and clear to minimize the reviewers' work. Make it easy for them to understand your ideas, locate information within the application and be your advocate. Be specific about what you want reviewers to know and what they need to know
- Follow application instructions exactly
- Take advantage of institutional resources for assistance in preparing your application and budget and submitting it as required
- Contact the funding agency's program officer as needed for information related to the agency's goals and procedures

All successful projects require planning, development, implementation and evaluation. Start early, seek collaborators and support, and note internal as well as external deadlines. Allow at least 3 months for writing the application. Consider carefully evaluation criteria to be used by reviewers to score your application.

Most funding entities have similar criteria for evaluating grant applications. The following discussion is based on the review criteria of the National Institute of Health of the U.S. Department of Health and Human Services. These criteria include: significance, approach, innovation, investigator and environment.[3]

Significance: Your study's significance must be made clear and concise and answer questions such as:

- Does the study address an important problem from the funding agency's perspective?
- If the aims are achieved, how will scientific knowledge be advanced?
- What will be the effect of your study on the concepts or methods that drive the field?

Approach: Your study's approach must answer such questions as:

- Are the conceptual/theoretical frameworks, design, methods and analyses adequately developed, well-integrated and appropriate to the aims of the study?
- Are potential problem areas acknowledged and alternative strategies considered?

Innovation: In addressing your study's innovation:

- Specifically state why you believe the proposed research is original and innovative, and offer examples
- Explain how your project challenges existing paradigms or requires developing new methods, techniques or technologies

Investigator: In addressing this criterion, answer the following questions:

- Are you appropriately trained and well suited to carry out this work?
- Is the work proposed appropriate to your experience level (and that of your collaborators)? Explain how the proposed study is similar to those you have already completed
- Does the investigative team bring complimentary expertise to the project?
- Are the contributions of each collaborator delineated?
- Have you included letters of commitment and consultation on appropriate letterhead?

In addressing the environment criterion, answer such questions as:

- How does your scientific environment contribute to the probability of success?
- Is there evidence of institutional support (e.g., a letter stating what your institution will provide)?

Grant Application Components

Abstract: The abstract, your research summary, may be the only part of your application reviewers read. The best approach is to write it first and revise it last when you know your final application content. The abstract states broad, long-term objectives related to the agency's mission, lists specific aims, concisely describes the research design and methods to achieve aims and highlights relevance to public health.

Specific Aims: The Specific Aims, the most important section of the grant application, should be well focused, not overly ambitious and hypothesis driven. It is critical to write them early, circulate them to your team of experts and incorporate their feedback before writing the rest of the proposal. Usually 2 to 4 aims are the norm.

This section typically includes 3 general sections:

1. The "set-up" paragraph, which explains the relationship between a pressing problem and your research theme. This paragraph should strongly persuade reviewers that the topic is important and worthy of their attention
2. The "specific aims" paragraph starts with a sentence like, "The specific aims of the study are to…" and then lists the aims. Each aim should allude to the techniques used to achieve each one. In listing the specific aims use active verbs, rather than passive ones
3. The "hypothesis" paragraph points to a specific problem or area and culminates in the statement of the hypothesis. Quantitative hypotheses contain PICO components: problem/population, intervention, comparison and outcome

Participants were provided with an example of specific aims to critique and edit in small groups by applying information discussed.

Background and Significance: This section must establish 3 things: the project is important, the science is interesting, and there is a high probability of success. This is not a literature review. Educate the reviewers to your way of thinking. Show how the proposed project builds on previous work and identify gaps in previous knowledge.

Preliminary Studies: This section should convince reviewers that you know what you are doing. Show that the work is feasible and that you have completed suitable groundwork.

Biographical Sketch: A formatted Biographical Sketch is used to convey information about the qualifications, productivity and the role of the key personnel involved in the proposed project. It is important to convince reviewers that you are highly qualified to carry out the project. A good biosketch includes a personal statement about the goal of the

proposed research and your related experience, employment positions, other experiences and professional memberships, honors, peer-reviewed publications and previous research support.

Workshop participants listed qualifications they would include in a biographical sketch and worked partners to brainstorm about enhancing their sketch.

Timeline: The timeline needs to clearly demonstrate that you can complete the project in the time allocated, be feasible, and realistic. A visual format is easier for reviewers.

Detailed Budget and Justification: Itemize and justify direct costs. Denote in-kind support and institutional requirements for indirect costs.

Conclusion: In conclusion, always remember that your application is a work of persuasion. It is not merely a description of the work you want to do. Rather you are making an argument that it is work that needs to be done, and that you are the right person to do it.[4]

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Techniques for Professional Presentation of Scientific Information

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Scientific presentations, whether delivered via posters or Power Point, are critical vehicles for disseminating cutting edge research findings.[1] Creating and delivering effective, informative and attention-grabbing presentations is no easy feat. Similar to written manuscripts, scientific presentations must be thoroughly planned, outlined and logically organized. Both the written and verbal elements of presentations are critical to the success of the whole package. The speaking and writing components of successful presentations can be taught, practiced and cultivated.[2] This workshop will discuss and detail the key elements to consider in the planning and delivery of quality scientific presentations. Topics addressed will include: creating compelling research posters and Power Point "slide shows" that incorporate visual appeal, timely content and enhanced readability, verbal delivery that considers word choice, voice flow and modulation, effective use of nonverbal communication such as eye contact and physical movement, use of approaches that appeal to different learning styles and developing a communication style that exhibits confidence, credibility and an element of fun and lightness to capture and keep the audience's attention.

Researchers who create effective scientific posters for presentation at professional meetings convey information succinctly, attractively and meaningfully. A poster should highlight the key components of a research manuscript; i.e., abstract, introduction/background, methods, results, discussion and conclusions. Attractiveness and readability are 2 major features of a well-done poster. To create visual appeal, provide different options for information giving that "pull in" the viewer. Text should be balanced with photographs, tables, graphs and/or charts. Too much text can be overwhelming and can detract from the key "take home" points. Graphics enable the concise presentation of data. Bulleting is useful for presenting a listing of information, such as delineating steps in a methodology. Font size and style must be considered as well as color. As with Power Points, too much color or the use of harsh color will deter viewers. Color has an effect on how information projects.[3] Other important elements to address include: judicious use of diverse graphics, incorporating main and subcategories to emphasize the importance of information, grammatical and punctuation parallelism, using spacing to enhance readability and key points and appropriate color variation. Posters must be titled appropriately and computer printed on high quality glossy paper. Appropriate references and institutional/corporate logos also must be included in the final poster.

Power Point presentations are another means for delivering scientific information. Some describe Power Point as the prima lingua of science since its presence in research presentations is ubiquitous.[1] The creation of effective Power Point slides (and handouts), i.e., the written components of an oral presentation, can be achieved through adherence to relatively straightforward yet critical standards or foundational guidelines. These guidelines serve to enhance audience receptivity and learning; they consider slide/content readability, viewer comprehension and the prudent use of multiple media techniques and movement for maintaining audience interest. A partial listing of elementary guidelines for successful creation of Power Point presentations includes:

- Using bullets versus complete sentences
- Keeping slides crisp and simple
- Limiting the amount of content per slide
- Selecting appropriate slide lay-outs
- Using templates that are kind to the eye and help control spacing and printing options
- Applying unity of design

Hand-outs are accompaniments to the verbal presentation and offer supplemental information that, for lack of space or other reasons, may not have been included in the slide show. Hand-outs also may reiterate and emphasize key points. They should be professionally printed. Many of the guidelines stated above apply to hand-outs.

The verbal component of the oral presentation is paramount. Power Points should be used for enhancement; the audience can read so the presenter need not and should not read slides.[3] Presenters must be tuned into their audiences. By maintaining eye contact with the audience, the presenters will know if they have captured or lost the audience. If attention seems to be waning, a different tactic should be adopted; e.g., voice modulation, a slide that shifts the tone or the presenter may ask the audience if they understood the previous point.[3] Frequent summarizations or reiterations help hold the audience's attention. Other key speaker rules include:

- Beginning the presentation in a manner that establishes rapport
- Honoring starting and ending times
- Speaking slowly and loudly

- Stepping away from the podium, if possible, in a non-distracting manner to help engage the audience
- Using good posture
- Encouraging, repeating and paraphrasing questions so that all audience members can hear and be engaged

Givens include the need to know the presentation material thoroughly, having the ability to roll with technological challenges and acknowledging others' contributions when appropriate. Ideally, the audience should feel that the presenters are passionate about their topic, enjoy being in front of the crowd and is able to say "I do not know" when an unanswerable question is posed.

In summary, the research community relies on scientific presentations as a means to disseminate and gather information, to consider new theory and to craft future research to generate new knowledge. Sophisticated technology allows for the delivery of scientific presentations that reach audiences around the world. Visuals, in the form of Power Point and poster presentations, accompany the majority of these presentations. Thus, the researcher of today and tomorrow will benefit from skills in creating effective visuals and in communicating compellingly and professionally.

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Writing For Publication in Scientific Journals

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Writing and contributing to the scientific literature is necessary for the progression of a profession. The American Dental Hygienists' Association has adopted the National Dental Hygiene Research Agenda which provides direction to dental hygienists on priority research areas that can help advance the profession of dental hygiene. While conducting research is vital to growth of the profession, if investigators do not write and publish the results for public review and critique, it does little to advance the status of the profession.

Writers can contribute to the literature by writing various types of manuscripts. Examples include letters to the editor, case reports, a review of the literature, short reports on a topic of interest, book reviews, systematic reviews and original research. This paper will focus on the publication of original research in a peer reviewed, scientific journal.

When planning to write a paper, it is important to determine the type of publication one wishes to contribute. Dental hygienists have several magazines and journals from which to choose. The journals that will have the most significant impact for moving the profession forward are those that are categorized as scientific, peer reviewed publications. For example, the Journal of Dental Hygiene, Journal of Dental Education and Journal of Dental Research are all examples of publications that are highly respected and publish results of original research investigations. Publishing in journals that are peer reviewed is important because readers know that the papers have been subjected to a rigorous review process by experts in the field that includes an evaluation of the research methodology, statistics and outcomes for accuracy, content and clarity. Another important aspect of the publication of original research is that it is published in a journal that is accessible via MEDLINE so that readers from around the world can access the article.

Following are guidelines for writing an original research publication for a peer reviewed, scientific journal:[1]

1. The first step is to decide on the journal to which the paper will be submitted. Once this has been determined, it is imperative that the author(s) thoroughly read the Guidelines to Authors to ensure that the paper is written in the correct format. When an author fails to strictly adhere to the required format, it is an automatic "red flag" to reviewers that other flaws may exist.
2. Abstract: The abstract is typically written last, but it is placed at the beginning of the manuscript. The abstract should provide a complete overview of the article including the question posed in the study, methodology, results and conclusions. The abstract should provide the major points of the paper.
3. Introduction/Review of the Literature: This section introduces the topic and communicates why the information is applicable or important. It states the problem and reviews the current knowledge related to the subject, points out gaps in the current knowledge, and sets the stage for why the current study was needed. Typically, journals do not require or allow a long introduction or review of the literature, so it is imperative that writers prepare a succinct section that reviews only the most important studies. Many writers think they have to review and include every article that has been written on the topic. Reviewers want to know that the writer has included the most important literature. Quantity does not always equal quality when it applies to an introduction and literature review.
4. Methods and Materials: This section should provide the reader with enough detail such that the methodology could be duplicated, including statistical tests used to analyze the data. If the author has conducted a survey, for example, they should provide samples of the questions asked in the questionnaire. Was the survey pilot tested prior to distribution to the test audience? Was it approved by an Investigational Review Board? Is the study set up to get positive results only? Was there a control group, if appropriate, for the methodology? Are subjects randomized in groups so that control and experimental groups are comparable or equal at the start of the study? It is important that studies be designed so that every obstacle that might interfere with getting objective results is accounted for before study initiation.
5. Results: The results section should report the findings from the data collection. Since this section is sometimes difficult for readers to understand, writers should use every available resource to present the results in an understandable and accurate way. Use of tables, charts and figures are one way to provide a visual display of results. Text should be used to emphasize important findings but it should not duplicate what can be found in the tables and figures. Tables and figures should be easy to read and interpret. The reader should not have to refer back to the text of the paper to understand what was presented. Many investigators will have a statis-

tician who will help them with the analysis of results. These experts can be extremely beneficial in helping the author(s) with the writing of this section of the paper.

6. Discussion: The discussion section should bring all of the elements together. It can be one of the more enjoyable parts of the paper to write because the author can provide his/her opinion and or speculate why certain results were achieved. In all other parts of the scientific paper, strict guidelines and content must be adhered to but the author has freedom in the discussion section to have an opinion as well as to suggest future directions for research related to the topic. The discussion section should also compare the results found in the study to previously published papers and speculate why similarities and/or differences were discovered.
7. Summary or Conclusions: The summary and conclusion section should be short and concise. Authors should not reiterate the results section but should briefly restate the problem, procedures and findings. No new information is introduced.
8. Acknowledgements: If an author has received funding for the project, this should be acknowledged in the paper in the acknowledgement section at the end of the summary section. In addition, authors should acknowledge a conflict of interest where one might exist. For example, if the author has received research funding from a corporate entity and one of the authors is a member of that company's scientific advisory board, this must be acknowledged. It is not necessarily a negative implication for the paper, but the relationship should be disclosed.
9. References: Every writer is ethically responsible for ensuring that the references cited are the most current ones available. Occasionally, references are cited from classic studies if no current studies have been conducted. The references should support the theoretical basis for the research results and conclusions.[2] Only original references (not secondary references) should be cited, and they should be references the writer has personally read for accuracy.

Readers rely on references to be accurate and obtainable. Web references should adhere to strict guidelines by the journal and be accessible to the reader. In general, references should be cited from peer reviewed references and not professional magazines. Also, many journals have limitations on the numbers of references that are deemed acceptable. This requirement is typically stated in the Guidelines to Authors.

Once the paper has been written, authors should have the paper reviewed by individuals who are either content experts or excellent scientific writers, or both. Many authors make the mistake of submitting a paper for publication without having it critiqued. This oversight can delay the review process.

When a paper is submitted to a journal, the editor will decide if the paper is appropriate to send to peer reviewers. Sometimes papers are returned to authors if the paper is not in the correct format or if the editor does not think the paper is appropriate for the journal. Otherwise the editor will approve for the paper to be sent out for peer review. This process may take several weeks or months. Once the first reviews have been returned to the editorial staff, they are then sent to the authors. Occasionally, papers are accepted on the first attempt but most often, the authors are asked to make revisions to the manuscript. Timelines may be incorporated in the review such that writers need to make the revisions and return it to the journal within a few weeks. If authors do not adhere to the timeline, the paper will be treated as a first submission and sent to new reviewers.

When authors submit revisions back to the journal, it is imperative that they also include a written response back outlining every revision they have made according to the request of the reviewers. This simplifies the process for the reviewers and ultimately expedites the publication process.

Of course, the final reward is seeing the paper published and knowing that a contribution has been made to the scientific literature in the author's field. Although the process becomes easier with time and experience, it is a journey that takes effort. However, the effort is worth it once the author sees his/her paper in the peer reviewed literature. Challenge yourself to become a writer and contribute to the dental hygiene profession.

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Keeping Current: Clinical Decision Support Systems

Jane L Forrest, RDH, EdD; Syrene A. Miller, BA, RDA; Greg Miller, DDS

The desire to improve the oral health of patients must start with the clinician's commitment to keep up-to-date with important and useful scientific knowledge. Although the desire may be there, the increase in the number of published articles, new devices, products and drugs has made it nearly impossible to do so. In fact, studies have shown there are widespread discrepancies among practitioners and their ability to stay current, and in some cases those variations are beyond the range of acceptability. Consequently, we now need specific skills to know how to access and critically appraise what we find, to see if clinical articles are valid and relevant. The challenge for dental hygienists is to integrate new knowledge whenever it is needed in order to provide the most appropriate care to their patients.

The combination of evidence-based skills and having computers or mobile devices with access to online databases and clinical resources begins to address this challenge. Evidence-based decision making (EBDM) incorporates the skills necessary for life-long learning that are an important part of the decision-making ability to understand, translate and apply relevant scientific evidence to patient care. This goes beyond the skills that most practitioners learned in their formal education. Therefore, this workshop is designed to introduce participants to basic EBDM concepts and skills, and clinical decision support (CDS) resources that can be used in education and practice through using case scenarios.

EBDM Concepts and Skills: EBDM is the formalized process of using a specific set of skills for identifying, searching for and interpreting clinical and scientific evidence so that it can be used at the point of care. The scientific evidence is considered in conjunction with the clinician's experience and judgment, the patient's preferences and values and the clinical/patient circumstances.[1] Thus, optimal decisions are made when all 4 components are considered.

It is important to understand research designs and the corresponding level of evidence that results from a research study. For example, knowing the level of evidence helps guide clinicians in locating appropriate research studies and then decide about whether or not they can place confidence in the findings. Since not all evidence is equal, a hierarchy of evidence exists to guide clinical decision making.[2]

The hierarchy consists of 2 categories of evidence sources: primary, or original research studies and secondary, or pre-appraised or synthesized publication of the primary/original research. Pre-appraised means that the research evidence has undergone a filtering process to include only those studies that are of higher quality, and they are regularly updated so that the evidence accessed through these resources is current.[3] Figure 1 illustrates the hierarchy[4] and the division among the 2 categories of evidence sources.

The "gold standard" for treatment questions includes the meta-analysis or systematic review (synthesis of 2 or more randomized controlled trials (RCTs) answering the same question). Also considered at Level 1 is an individual RCT. Ideally, this level of evidence is used in preparing clinical practice guidelines. These are followed respectively by cohort studies (Level 2), case-control studies (Level 3), case reports (Level 4) to studies not involving human subjects. Although each level of the hierarchy may contribute to the total body of knowledge, "...not all levels are equally useful for making patient care decisions."[5] As you progress up the pyramid, the number of studies decreases, while at the same time their relevance to answering clinical questions increases. Recognizing the level of design used to answer a question is important to evidence-based clinical decision-making.

Hierarchy of Pre-Appraised Evidence: To streamline the integration of research into practice and make it more user-friendly for practitioners, clinical decision support (CDS) resources are emerging to simplify access to relevant, usable information. Many of these resources are pre-appraised and are presented in an easy to read format that allows the user to minimize the time needed to digest the information, learn of its clinical application and determine its relevancy to the patient problem or question at hand. (Figure 2) "The goal of CDS is to provide the right information, to the right person, in the right format, through the right channel, at the right point in workflow to improve health and health care decisions and outcomes."6, p.13

Computerized Clinical Decision Support Systems (CDSS) are at the top of the hierarchy3 and require input of patient-specific clinical variables in order to provide patient-specific recommendations. At this level, the individual patient's electronic health record is automatically linked to a database that can provide the current best evi-

dence for his or her specific circumstances. This assists the clinician by providing suggestions for appropriate care, warning of possible adverse drug events and applying new information through the analysis of patient-specific clinical variables.

If a CDSS does not exist, the next best step is to look for Summaries. In dental hygiene and dentistry, these include Clinical Practice Guidelines (CPGs) that are based on a full range of evidence from the lower levels (individual studies/synopses of systematic reviews). Guidelines integrate evidence-based information about specific clinical problems and provide regular updating. CPGs are broader in scope and provide more general care and treatment suggestions than CDSS. CPGs often can be found on the websites of specific associations and organizations including the:

- American Academy of Pediatric Dentistry (http://www.aapd.org/media/policies.asp)
- American Academy of Periodontology (http://www.perio.org/resources-products/posp-pr3-1.html)
- American Dental Association, Center for Evidence-based Dentistry (http://ebd.ada.org)
- Centers for Disease Control and Prevention (http://www.cdc.gov/OralHealth/guidelines.htm)
- Agency for Healthcare Quality and Research (www.ahqr.gov)
- American Heart Association (http://www.heart.org/HEARTORG/)

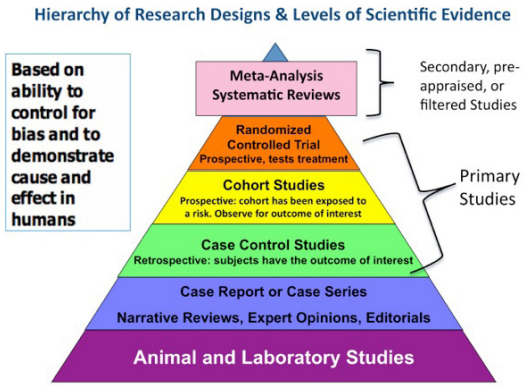
If no evidence exists at the Summaries level, the next step would be to look for Synopses of Systematic Reviews, which can be found in such journals as the Journal of Evidence-Based Dental Practice and Evidence Based Dentistry. Each journal provides a 1-2 page peer reviewed critical summary of an original systematic review with expert commentary so that the reader is able to quickly determine if it is clinically relevant to the patient.

If no evidence is available at this level, then search for individual Systematic Reviews, which can be found through such databases as PubMed, the Cochrane Library and the American Dental Association's Center for Evidence Based Dentistry. Finally, the bottom two levels relate to primary research studies. A Synopsis of single studies can be accessed through PubMed and also found in the evidence-based dentistry journals, and an individual single study also can be accessed through PubMed.

Emerging CDS Tools/Use of Mobile Technology: The infrastructure to support the application of evidence at the point of care is evolving. Not everyone has a computer chairside or is using an electronic record. However, evidence resources can be accessed via the Internet and many important topics for dental hygiene can be found. Having Clinical Decision Support tools can enhance the use of the most relevant clinical evidence in making 'real-time' decisions chairside when they are needed.

CDS includes a variety of printed and electronic tools that make knowledge readily available to help make more informed and individualized health care decisions. Some of these tools include computerized alerts and reminders, drug-dosing calculators, antibiotic management, clinical guidelines, and patient data reports. Having an electronic health record also allows a provider to quickly read legible information in the office and to access the record when away from the office.

Figure 1: Hierarchy of Scientific Evidence and Research Designs for Treatment Questions



Hierarchy of Research Design. Modified from the Evidence Pyramid. Copyright permission granted by SUNY Downstate Medical Center, Medical Research Library at Brooklyn, http://library.downstate.edu/EBM2/2100.htm[4]

Figure 2: The 6S Hierarchy of Preappraised Evidence

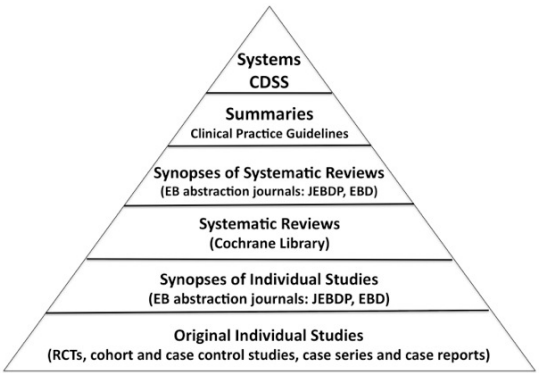


Figure adapted from the 6S Hierarchy of Preappraised Evidence by DiCenso A, Bayley L, Haynes RB. ACP J Club, 15 September 2009;151(3): JC3-3.

For example, if a patient calls the office needing a prescription, the patient can be verified as a patient of record, and the health history, treatment record and radiographs reviewed remotely via a smart phone. A prescription can then be called into the pharmacy or an e-prescription sent.

Using alert systems and accessing electronic resources through the use of mobile devices are becoming the norm. For example, journals will email their Table of Contents, which can be scanned for articles of interest. Sites such as MedScape and PubMed have specific apps for mobile devices, so again, information is at your fingertips 24/7.

Conclusion: Clinicians are inundated with information and struggle to keep current with an ever increasing knowledgebase. The development of evidence-based skills are necessary to enhance the movement of research information to the point of care (chairside) in order to ensure that better treatment decisions are made that will help improve oral health outcomes. The hierarchy of evidence helps the clinician understand research design and the corresponding level of evidence for primary and secondary research. CDS resources also are available that analyze the quality of research and synthesize study results in a precise summary. These emerging tools are designed to streamline the integration of evidence into practice.

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Overcoming the Fear of Statistics: Survival Skills for Researchers

Karen B. Williams, PhD, RDH

ANOVA. Hierarchical linear analysis. Quadratic function. Mixed effects models. Sphericity. Heteroscedasticity. Collinearity. Non-parametric tests. A priori. Post hoc.

Statistics? Sadistics?

Statistical terminology and formulas typically evoke a natural reaction of distress, apprehension or outright fear in many researchers, both novice and experienced alike. I hear many people say: What do these terms mean? I don't understand this jargon. How do I decide which test to use? What is a power analysis? How do I grow as a researcher when I feel intimidated by statistics? Where can I get help?

Introduction: In the 1800's Benjamin Disraeli, a British Prime Minister, was thought to have quoted that there are "Lies, Damn Lies and Statistics." Some have also attributed this quote to Mark Twain. Even today, the lay public is highly suspicious about statistics and prematurely conclude that all statistics are misleading or distort the truth. Even among clinicians, researchers and scientists there is a general misunderstanding about the meaningfulness, usefulness and shortcomings of statistics in application. I cringe when I hear scientist/clinician researchers state, "The differences between groups were highly significant at p=0.008. The result of our study proved X causes Y." Inherent in these comments are 2 common fallacies. The first is that a small p value is evidence of "truth" and the second is that smaller values can be construed as a large effect. In order to understand why these assumptions are fallacies, it is important to know what the p value does and does not represent.

In research, the accepted convention for separating systematic explanations (X causes Y) from chance explanation (sampling error or measurement error) is based on testing the null hypothesis. Sampling error can occur if treatment groups differ simply by chance. Random assignment, the accepted process for assigning individuals to intervention/treatment groups in experimental research, removes procedural bias but it does not ensure that groups are equal with respect to all factors that might influence the outcome. Error can also be introduced into the data as a function of how, when, where and by whom outcomes are measured. Because both of these sources of error exist, they introduce doubt that differences between intervention/treatment groups in the outcome (Y) are solely attributable to the intervention (X). This makes it impossible to "prove" that X caused changes in Y.

We can, however, estimate the likelihood that any observed differences between groups are solely based on chance variation or dumb luck – via the null hypothesis. Abelson aptly points out that testing the null hypothesis using statistical tests is a "ritualized exercise of devil's advocacy."[1] The null hypothesis is an artificial argument that any difference between intervention/treatment groups is due to chance; it also assumes that the treatment has no effect on systematically affecting the outcome. Researchers hope that the likelihood of this is really small. The p value derived from statistical testing provides that estimate – the probability that, assuming the intervention is not effective, the intervention/treatment groups are different due to chance variation. If a small p (conventionally <0.05) is obtained, then the researcher can reject the assumption of difference likely due to chance and accept the more logical alternative – that differences are likely due to the intervention/treatment (an interesting note is that the 0.05 was established years ago and has become an accepted standard, although the researcher could just as easily determine 0.1 to be the critical p for determining significance). Notice in this description that the issue is about making a logical argument based on the most likely explanation.

The second statement, that a smaller p value can be construed as a bigger effect, is fundamentally inaccurate. The p value is strongly influenced by 3 factors: the magnitude of the effect (effect size measure), the sample size (number of observations in the study) and the amount of variation in the data (commonly the standard deviation). Because sample size drives magnitude of the p value, it is inappropriate to equate it with large effect size. The effect size is a different issue and can be computed 2 ways – the raw effect size (difference between group means) or standardized effect size (the raw effect size divided by the standard deviation). From a clinical perspective, it is helpful for researchers to think about raw effect size as the minimally important difference, which is the smallest difference in mean scores that would be considered meaningful. The standardized effect size, which takes into account the amount of variance, is a more valuable index and can be used as a measure of importance. Because it is not influenced by sample size and is independent of the measurement scale from which it is derived, it gives an objective estimate of the strength of association between the outcome and intervention/treatment. Common effect size measures include r^2, eta squared, odds ratio and Cohen's d.

The effect of sample size on the p value cannot be overlooked when interpreting statistical tests. The sample size has a direct influence the magnitude of the p value. A study with 1,000 subjects will always have a much smaller p value than a study with 100 subjects, given the same effect size or magnitude of difference between groups. Power of a statistical test (the likelihood of rejecting the null hypothesis when there is a real difference) is largely determined by the number of observations/sample size.

Finally, it should seem intuitive that if there is a large amount of variance in the outcome, the effect size will be smaller and thus the p will be larger. The bottom line is that if researchers want to get a very small p value in a statistical test, they will use a large number of subjects, will attempt to maximize the effect of the intervention and minimize the amount of variation in scores. For example, several years ago a product was developed that appeared to have good antimicrobial properties in vitro. The clinical trial used a very large sample size, had very stringent criteria for selection to limit the amount of variation between subjects and had subjects withhold oral hygiene to maximize the effect of the antimicrobial. The results of this trial showed a statistically significant reduction in plaque (<0.05) and gingivitis (<0.01). The study design maximized all factors associated with the p value. Subsequent studies that had a broader group of subjects using the product in addition to brushing failed to show statistical significance.

So, why is it that intelligent individuals are so hasty to equate getting a p value of <0.05 with truth and meaningfulness? Is this convention wholly accepted in the scientific community? The answer is, not necessarily. As early as 1978, Carver succinctly spoke out on the "fantasy" of statistical testing to provide proof of the hypothesis and then argued for caution in interpreting statistical significance.[2] In 1993, he expanded this premise of caution and added suggestions for logical interpretation of data along with use of the p value, effect size estimate and replication.[3] Since then, standards have shifted towards a more rational application of statistical testing. Probably the best example is the development of the CONSORT Guidelines for publication of clinical trials, The Improved CONSORT statement and guidelines now suggest that researchers provide information about what would be a meaningful minimally important difference in outcome, that this difference be defined in advance and that value be used as the effect size in designing and planning clinical trials.[4] Despite changes in publication standards and improved statistical techniques available via desktop programs, there is still a tendency for clinicians and researchers to fear statistics and make rash judgments about the meaningfulness of statistical analyses.

Humans innately have a need for certainty. When individuals feel uncertain and there are numerous cues to be considered simultaneously, there is a tendency to rely on one-dimensional rule-based decision making.[5] Such is the case with statistical analysis and interpretation. As Carver stated in 1995, multiple cues must be considered in order to derive valid conclusions based on study design, statistical output and exploration of defensible interpretation. Adding to this, clinician/researchers know the importance of statistics in research, but only a small percentage can proficiently conduct analyses and interpret results with confidence. In point, a cross-sectional study of faculty, residents and students at the Mayo Clinic showed that although 87% felt that training in biostatistics was important, only 14.6% felt that they could meaningfully conduct and interpret their own statistical tests.[6] While there are no comparable studies on dental or dental hygiene researchers, anecdotal evidence suggests that few clinician/researchers are comfortable and confident with biostatistics. My personal experience over the last 2 decades is that, in fact, most regress to a position of apprehension that leads them to abdicate the responsibility to a statistical consultant. In fact, that can be a very good strategy. However, getting a good statistical consult requires a level of understanding, active engagement and advanced preparation.

The goal of this workshop is to help demystify statistical testing and provide realistic strategies that can be used to improve the quality of one's own research efforts and make getting a statistical consult an opportunity for growth and clarity. I will focus on the role statistics play in helping researchers make a cogent, logical and supported argument for any research findings. In and of themselves, statistical analyses provide only 1 piece of information in the larger puzzle that needs to be considered in making a persuasive argument about the results of a study. Let us start at the beginning and outline the basics of making sound judgments regarding statistical validity in research.

The Logic of Establishing Causality: When attempting to establish whether some treatment, characteristic or intervention causes real change in a given outcome, some basic criteria must be met. At the very least, there must be a logical or biologically plausible relationship between the cause and the outcome. Simply stated, logic must prevail at the most fundamental level.

Let us take a simple example. A researcher is interested in determining if hydrogen peroxide (H_2O_2) is effective in reducing gingivitis. In vitro research has demonstrated that H_2O_2 affects gram negative and gram positive organisms though the release of

oxygen. So we can say that the first criterion of "biologic plausibility" is met. Secondly, exposure to the cause must precede development of the outcome. Back to our example of H^2O^2 and gingivitis, we obtain a group of individuals with clinically evident gingivitis (defined as having at least 40% of sites that bleed on probing (BOP)). The subjects are given an H^2O^2 product to use twice daily for 3 months and BOP is assessed at this point. If change occurs, at least we have met the criterion that the intervention precedes change in the outcome. Third, there has to be an evidence of strength of association. In other words, there is an actual relationship between the suspected "cause" and the outcome. In our example, we also randomly assigned subjects to receive the active product and a sham product without H_2O_2. We observe a reduction in the H_2O_2 group of 15% BOP whereas the sham treatment group shows no change. From this we can estimate the size of the effect using one of the effect size measures discussed earlier. We could also assess a dose-response relationship by having 3 groups (1 sham group that receives product without H_2O_2, 1 group that receives the product with 3% H_2O_2 and 1 group that receives product with 10% H_2O_2). If results show a gradient effect on BOP reduction such that the sham group <3% H_2O_2 group <10% H_2O_2 group, good evidence of causality exists because one can link "amount of intervention" with "amount of outcome."

Fourth, and critically relevant to both proper design and statistical testing, is that there has to be a lack of competing explanations. In our example, the study would have to have been designed to standardize other oral hygiene methods (brush, dentifrice, flossing and frequency of rinsing) at a minimum, but there also might be a need to explore the data for other possible explanations, such as whether groups were equivalent in amount of gingivitis at the start or differed regarding relevant factors (gender, age, etc.) that might impact amount of BOP reduction. Ultimately, the question of whether change in outcome is attributable to factors other than the intervention gets at the degree to which researchers are willing to confront their own confirmation bias. We will address that more in the next section on Comparison.

Lastly, one needs to consider the consistency of the evidence. A single study does not provide sufficient evidence to support causality, although it may contribute to the body that will eventually establish "proof." The important question is whether the results can be replicated in different samples, by other researchers and in different settings. In our example, let us say that these results show a clinically meaningful and statistically significant effect favoring the 10% H_2O_2 product compared to both the sham and 3% groups. That would provide preliminary evidence to support causality; however, unless these results are replicated by others using similar methodology, the argument for causality cannot be supported over time.

Comparison: Most, if not all clinician/researchers would argue that good design is fundamental to confidently conclude that X causes Y, irrespective of results from a statistical test. Applying good statistics to poor quality data is like putting perfume on a pig – it might smell better but it is still a pig. Certainly, having a comparison group (or better yet, a control group if possible) is necessary in order to tease apart whether any observed changes are attributable to whatever intervention (or possible causative variable) is being imposed on subjects or might result from other factors. It is through the counterfactual model that we can observe the "effect". If we impose some treatment/intervention on one group of individuals, we must also have a different group of individuals (who are relatively the same) who do not receive the treatment/intervention – any difference we observe between the groups should give us some estimate of the "effect" of the treatment/intervention.

Comparison then is a necessary element for establishing causality of a treatment or other intervention. Statistical tests allow us to decide if the difference between groups is what one would expect simply because groups vary. If it is unlikely that one would simply (by chance) have groups that differed on the target outcome by a certain magnitude, the statistical test will give us an approximate estimation of the likelihood of that event. Now, herein is the rub. While the statistical test (and associated p value) can give us an estimate of chance differences, it is not sufficient. There are always other competing explanations for why the groups might or might not have differed – and these require applied logic and consideration. These can include factors too numerous to mention, but some might include:

- Individuals in the respective groups looked the same but differed in subtle ways that we were unable to detect up front (despite randomly assigning them to groups)
- While observing people over time, what we were observing was naturally changing (e.g. aphthous ulcers and healing)
- Our measurement strategy was problematic or unequally implemented
- The study timeline was insufficient to capture real change over time
- There were missing data because not all subjects were available for all observation periods or some dropped out of the study
- There were too few subjects to capture a differ-

ence if it existed or there were so many subjects that even a trivial difference would be found to be statistically significant

The bottom line: Hypothesis testing using statistical test gives us one piece of information that is important to a larger decision process – determining the likelihood that some intervention/treatment is causally related to the outcome.

Using Statistical Tests as Part of a Logical Argument: One of the most compelling books in print today is Statistics as Principled Argument.[1] Abelson argues for use of applied logic and good judgment along with hypothesis testing to make good decisions about study results. Like Carver, he posits that for any difference observed in a study, several possible explanations are possible. In this regard, statistics, along with applied logic, can assist the researcher in exploring for and identifying possible alternative explanations. Psychologists have demonstrated repeatedly that people, even researchers, are highly susceptible to confirmation bias. Confirmation bias results in people selectively focusing on information that reinforces preexisting beliefs and ideas. Confirmation bias can result in overestimating the influence of systematic factors (like an imposed treatment) and underestimating influence of alternative explanations, including chance. The tendency to jump to the conclusion that an intervention is effective, especially if there is a p value from a statistical test of <0.05, without thoughtful consideration.

Being aware of confirmation bias, recognizing the human tendency to simplify complex decision making and developing a systematic approach to considering results is the hallmark of a good scientist/researcher. Abelson proposes a systematic approach aimed at creating a persuasive argument with the data, statistical analysis and data presentation.[1] Abelson's approach is valuable for consumers of research, but has distinct utility for researchers in the data analysis and writing phases. The approach is based on what he calls the MAGIC criteria. This acronym stands for: Magnitude (think effect size or magnitude of association), Articulation (specificity of detail that might include exploring an observed effect on subgroups or in different contexts), Generality (framing results within the appropriate context or across contexts if possible), Interestingness (given the results, how does this change the field of knowledge) and Credibility (results are conceptually grounded, logical and supported given the methods and statistical analysis). I encourage dental hygiene researchers to get this reference - learning to apply these criteria to one's own research has the potential for improving evidence used in patient care.

It should be obvious at this point that statistics and statistical analyses sit within a much larger topic of "quality of evidence" that includes design, conceptual framework, critical thought and unassailable logic. Viewed this way, statistical tests should be considered as one of many decision tools that researchers need to derive valid conclusions about their results. Since very few clinical researchers also have the depth of understanding that underlies the field of statistics and biostatistics, they are likely to not be sufficiently aware of how these tools can be used to their maximal benefit to answer meaningful research questions. Actively seeking out a consultation with a biostatistician with experience in the broad field of health-related research is one of the most effective ways to overcome a fear of statistics.

Getting a Statistical Consult: Obtaining a statistical consult and power analysis during the design phase of a study is one of the best ways to circumvent problems, maximize efficiency in the research process and reduce one's fear of statistics. There are always competing approaches that change the manner in which the study is conducted and data are analyzed. Addressing these during the planning phase will make the research process much less stressful and will promote high quality research. At our institution, we have a Research and Statistical Consult Service that is available at no cost to health care researchers. Many institutions have similar services or have individuals on the faculty who provide comparable services. Check to see what is available to you. Find someone who is knowledgeable with whom you can discuss your project.

Once you have identified a person or service, prepare for the consult in advance so that you have relevant information at hand. Review the literature relevant to the topic so that you are well prepared for the questions that the statistician will ask during the consult. Be aware that it is not sufficient to do a shallow review of the literature. As you review the literature, be attentive to how results may have changed over time. An interesting observation about study results is that effects often decrease over time. Lehrer suggests that "truth wears off" over time because our illusions about the meaningfulness of various research question declines over time. Paying attention to this and being able to articulate this trend will be important for conducting the power analysis. Having the right estimate of sample size up front will improve the likelihood of planning a doable study and having meaningful results.

In advance, draft an abstract that summarizes the project using the PICO format. In doing so, consider the following:

Population: What is the population being studied? It is helpful to know as many details about this population in advance. For instance, if the researcher is interested in targeting a specific condition, what is the prevalence of this condition in the target population? Is there a range of severity that must be considered? What other factors are related to the condition that might influence selection of subjects or design of the study?

Intervention: What is the intervention or exposure variable? What is the proposed mechanism of action of the intervention or exposure variable? Is there a threshold of intervention or exposure that needs to be considered? What have previous studies shown with respect to variations in response (effect size) for the intervention? How has the intervention/exposure variable been defined?

Comparison or Control Group: What is the most appropriate comparison or control group? What would comprise an appropriate comparison group? For experimental clinical trials, is there an attention control that could be used in lieu of no treatment? If this is an observational study, is there a comparison group that is sufficiently similar to the target group that would allow fair comparisons? For observational studies, selection of the appropriate control or comparison group can largely influence the results.

Primary Outcome Measure: What outcomes are feasible to measure? How can the primary outcome be operationally defined? Are there secondary outcomes that should be captured as well? Given these operational definitions, how have these outcomes been previously measured? Is it possible to obtain measurements in a valid and reproducible manner? If using an existing instrument, what is known about using the instrument? Under what conditions can this instrument be used? What is the unit of measurement and characteristics of how attributes of the outcome are quantified (measurement scale)?

Approach the consult with an open mind. A good consultation will usually result in modifying some aspects of your original research plan. Be prepared to capture the important recommendations from the statistician – either in writing or audio recording. Clarify any areas that seem confusing at the time. A good consultant will help you identify potential confounding variables that should be controlled either by design or statistically controlled. Make sure you leave with an understanding of how the design, measurement and statistical analysis pieces fit. Once you have drafted a proposal (comprehensive design and analysis plan), get confirmation from the consultant that you have "gotten it right."

During the consult, discuss how you will set up your data set for analysis. The statistical analysis plan, design of the study, capture of confounders, number and type of outcome measures and statistical software will dictate how your data should be entered. Unless you are completely comfortable with the statistical software and analysis plan, do not do this on your own. There is nothing more frustrating than to have all of your data entered, only to realize that it is not analyzable in that format. Most importantly, enjoy the process. Leave your apprehension at the door and look at the consult as a unique opportunity to engage in creative planning.

Statistics are wonderful tools that help researchers plan, implement and make sense of their data. Effective use of statistics, while grounded in math, really relies on applied logic. Statistical programs manage the computational aspects of the process, but do not overcome bad design and incorrect analyses. Approach the research process just as you would plan a trip to a foreign country, and you can avert the fear of statistics and pain of failure.

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Getting Started In Clinical Research

MaryAnn Cugini, RDH, MHP; hristine Charles, RDH, BS; Janet Kinney, RDH, MS, MS

Research career opportunities and settings are varied and diverse. Areas include public health or epidemiological research, dental hygiene profession-based research, practice-based research, university research programs and corporate research, including basic clinical and product evaluation.

Interestingly, when asked about careers in research, some hygienists associate these opportunities with "lab jobs" or "desk jobs," leaving patient contact and clinical experiences behind. Basic science is a very necessary component of clinical research, but for those wanting to utilize their basic science training combined with clinical skills gained during practice, a career in clinical research may be of interest.

Career paths in any discipline have basic building blocks or steps that enhance the journey. For clinical research, the steps include clinical experience, advanced education, networking and mentoring. In fact, career paths in clinical research for the dental hygienist include the obvious – therapist or examiner – maximizing the clinical experience provided through dental hygiene training and patient care. More advanced roles include sponsor and/or principal investigator, coordinator/manager of the research project or, in the regulatory audit or quality assurance function, usually achieved after further education in the field of clinical research. Formalized educational programs have been created to train individuals from many professions for these roles in clinical research.

There are many educational programs offered for advancement in clinical research. A Google search using "clinical research training" yielded 18,400,000 results. Programs are varied and are offered at the university level (eg: full degree or certificate-granting), through private educational services companies and associations dedicated to clinical research professionals. For example, in the U.S., Drexel University offers an online master's degree in Clinical Research Organization and Management and a Master of Science in Clinical Research for Health Professionals, in addition to online certificate programs. Other universities and colleges offer similar options. A check of local area institutions is the first search to conduct when investigating further education. One example of an international educational program can be found at The University of Kent, U.K. Private educational services, such as Barnett Educational Services, offer online training and certificate programs in clinical research.

Two professional organizations dedicated to the support of clinical research professionals are the Society of Clinical Research Associates and the Association of Clinical Research Professionals. These organizations offer training and certification for Clinical Research Associates and Clinical Research Coordinators. Additionally, these sites offer current lists of available clinical research positions.

Mentoring and networking play important roles in getting started in clinical research. Students can begin by seeking guidance from professors involved in research. Practicing professionals can access information through national dental hygiene websites that contain lists of available mentors. Dental and dental hygiene schools are another source for networking. Schools are involved in conducting clinical trials and may be advertising for clinicians to participate as therapists and research subjects. Another important resource to consider is professional publications. Authors can be contacted to provide guidance as well as offer discussion in their area of research.

Important personal attributes that may help in a successful career in clinical research include strong written and oral communication skills, adaptability, being a self-starter, attention to detail and good time management skills. Success of a study highly depends upon a variety of people being able to effectively work together, so being a good team player is crucial.

This workshop will provide interactive discussions and presentations by clinical research from academia and private industry. The goals of the workshop are to:

- Provide the participant with a good understanding of the roles and responsibilities involved in a career in clinical research
- Explore the process involved in day to day conduct of clinical trials from the perspective of the sponsor and investigator
- Compare and contrast industry and academic research career pathways
- Learn about Dental Practice-Based Research Networks designed to train clinician investigators to study problems encountered on a daily basis in practice

Using role play and open discussions, the clinical trial process will be explored from hypothesis inception through publication of results. The workshop

format is designed such that attendees will gain an understanding of the skills, roles and responsibilities involved in all aspects of clinical research. The workshop will be given by 3 experienced research dental hygienists, each providing her unique perspective on her own career path, discussing the clinical research process from each of their experiences and providing insights from the academic, corporate and contract research organization perspectives.

MaryAnn Cugini brings her career experiences in academic and industry research settings to the workshop. She will share her regulatory experience and provide a basic understanding of the importance of maintaining protocol adherence and abiding to the regulatory standards of clinical research.

Having managed clinical trials for several corporate organizations and with independent clinical research organizations as well as academic institutions, Chris Charles will provide her insights regarding selecting and validating research sites and investigators, protocol development and the rigor surrounding conduct of clinical trials, and communication/publication of results.

Janet Kinney will speak about the importance of having clinical experience and good patient management skills prior to commencing a career in clinical research. In addition, she will share how educational training in the area of research methods helps to answer the "why" questions during the inception, development and conduct of studies. And finally, as a fairly new investigator, Janet will share with the audience her thoughts about the importance of networking and having strong mentors to help guide the newcomer during the early career years.

In summary, getting started in clinical research takes some concerted effort and forethought on your part. Prepare yourself by seeking educational opportunities that train you in the field, and then be proactive about building diverse networks and relationships with experienced people who are in a position to help you achieve your career goals. Once engaged in clinical research, exercise exemplary levels of confidentiality and protection of intellectual property and always be cognizant of your obligation to comply with Good Clinical Practice procedures and behaviors.

Whether you are a just starting a career in clinical research or are a well-seasoned professional, the field of clinical research offers challenging and exciting opportunities allowing for continual growth both personally and professionally.

Introduction to Preparing a Systematic Review

James D. Bader, DDS, MPH

The profession of dentistry has developed a store of specialized knowledge that serves as the basis for decision making. This knowledge base has evolved over time, as the methods for the creation, synthesis and dissemination of knowledge have changed. At first, dental knowledge was accumulated and synthesized through experience by itinerant dentists and barber surgeons, and dissemination was limited to master–apprentice arrangements for training new individuals.

As the profession matured in the late 1700s and through the 1800s, texts, journals and dental schools emerged to aid in the synthesis and dissemination of the knowledge base. But the creation of knowledge did not change radically until the 1900s, when results of formal clinical studies began to supplant experts' opinions as the most valued form of knowledge. As the number of studies on a topic grew, the literature review emerged as an important means for synthesizing the results of individual studies.

In recent years, changes in the synthesis and dissemination of the knowledge base that have been occurring signal the beginning of a new era. The preferred means of summarizing the literature that addresses a particular question topic is now the systematic review, an approach designed to minimize the biases inherent in the review process while at the same time improving the utility of the literature synthesis for the practitioner.

The Rationale for Systematic Reviews: Systematic reviews are designed to minimize the biases that are usually present in traditional literature reviews.[1] The most frequent sources of bias in traditional reviews involve not including all of the relevant studies and not combining the information from the studies in an objective manner that takes individual study weaknesses into account. In part, these biases arise because traditional reviews of the literature tend not to be well-focused on a specific problem. Traditional reviews tend to be non-specific, and as a result it is difficult to include and carefully analyze all of the relevant literature on the broad general topic the review purports to address. In addition, bias is likely to arise when the author of a review holds strong pre-existing opinions concerning the topic. It is human nature that decisions about what studies to include and how to synthesize the results will be influenced by these opinions.

Systematic reviews focus on specific clinical questions. This more narrow focus permits a much more careful and complete search and selection process to identify and include all relevant studies that have addressed the question of interest. Because systematic reviews are designed to maximize objectivity, they require the prior determination of search methods, inclusion criteria and evaluation criteria, which helps reduce the chances of bias in inclusion of articles in the review and evaluation of the strength of included articles.[2]

Steps in Performing a Systematic Review: The initial step in performing a systematic review is the formulation of a clinically relevant key question, which identifies 4 crucial "PICO" elements. These elements are the population or patient type (i.e., the individuals or groups for whom an answer is sought),the intervention (i.e., the treatment or clinical condition of interest), the comparison (i.e., an alternative treatment or control) and the outcome (i.e., the measures used to assess effects of an intervention).

The second step is defining criteria for including and excluding studies. These criteria arise from the key question and other considerations, such as study designs, publication dates and languages and details of treatment procedures. Careful definition of these inclusion criteria, together with the key question, will define the group of individuals to whom the results of the systematic review can be generalized. Criteria for assessing the quality of individual studies are also identified in this step.

The third step in performing a systematic review is designing a search strategy. Since systematic reviews attempt to identify all studies relevant to the key question, the search for such studies should be exhaustive. It characteristically includes searching electronic indices, such as MEDLINE, EMBASE and more specialized indices depending on the key question. Examination of reference lists of all potentially eligible studies identified in the initial stages of the search is a standard technique, and the "gray literature" should also be examined, including dissertations and theses, conference reports, abstracts and unpublished studies identified through inquiries to colleagues and manufacturers.

The fourth step involves the application of the inclusion and exclusion criteria to determine eligibility for every study identified in the search. Multiple reviewers do this independently and then follow a predetermined procedure for resolving disagreements. A written record is maintained of reasons for exclusion of studies.

The fifth step of a systematic review is abstract-

ing specific information from each included study in a standardized manner. Information includes details of the study design, subjects, methods and results, along with information needed to assess the quality of the study. The extraction process is usually performed independently by 2 reviewers. Where disagreements occur through error, they are corrected. When the problem is a matter of interpretation, a third reviewer may decide, or the authors of the study in question might be contacted for clarification.

The sixth step is the analysis and presentation of results of the systematic review. All extracted data are presented in an evidence table, which facilitates comparison of the included studies. A qualitative summary of these studies, based directly on the evidence table, is usually presented that provides an overview of the designs and findings of the included studies. In most instances, the study results are evaluated for heterogeneity or between-study differences. Depending on the extent of heterogeneity, study designs and data available in the published studies, the systematic review team may also conduct a meta-analysis of the outcome data.

The final step in the systematic review, interpreting the evidence, is the only step not guided strictly by the review protocol, and the only one where some subjectivity is permissible. Here, the review's limitations and the strength of the evidence are discussed, and applicability of the study results to the clinician is considered. Equally important, the systematic reviewers may identify implications for future research.

Systematic reviews are usually completed by teams, rather than individual authors. An advisory committee composed of both clinicians and researchers with expertise in the topic may be appointed to provide critical commentary concerning the key question, the inclusion and exclusion criteria, the final list of included studies, the completed evidence table and the draft final report. Such oversight acts as an important additional step in maximizing the likelihood that the review is objective.

It is important to remember that the structure of a systematic review facilitates, but does not guarantee, an objective summary of the evidence for a clinical question. Departing from accepted standards for conducting a systematic review will increase the likelihood that the results will be biased. The reader must then determine if the increased likelihood of bias is sufficient to render the review not useful. Checklists and guidelines are available that can be used to assess adherence to recommended practices and completeness of reporting.[3,4]

Whether the question addressed by the systematic review can be definitively answered by the review is not a measure of its overall quality. Surprisingly, the results of systematic reviews are often equivocal because either the necessary studies have not been done or the quality of the studies is judged to be insufficient to address the clinical question without bias. Thus, from the standpoint of clinical applications, a primary advantage of the systematic review is also one of its greatest frustrations: it not only tells us what we do know, but also what we do not.

This workshop summary is based on content that has appeared previously.[5] Reprinted with permission from the Texas Dental Journal.

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Design Considerations for Qualitative Research: Getting At Strawberry Milk

Alice M. Horowitz, PhD; Wendy L. Child, MS

Overview: This interactive workshop is designed to build dental hygiene researchers' confidence and skills for effectively using qualitative research methodologies, particularly focus groups and interviews, for oral healthcare research. The presenters' approach incorporates brief highlights of an institutional review board-approved qualitative research plan for, and preliminary findings from, a 2010–2011 Maryland qualitative and quantitative oral health study with pregnant women and parents of young children, and also with health care providers (dental hygienists, dentists, pediatricians, family practitioners and nurse practitioners). The study was conducted by the Herschel S. Horowitz Center for Health Literacy at the University of Maryland.

The workshop title refers to how qualitative methods, carefully and sensitively applied, can help researchers deepen their understanding of health beliefs, behavior and literacy and their origins among health care consumers, as well as the health care practices and beliefs about patients among health care providers, including oral health care and other health care providers. For example, in one focus group the presenters conducted, a young mother described her frustration with her baby's grandmother who refused to switch from chocolate milk in the baby's bottle to more healthful, fruit-based strawberry milk. The workshop addresses how to structure qualitative research to encourage candid, detailed and authentic responses, as well as ways to organize and utilize the findings, especially to help inform oral health education and oral health care practice and policy.

Following this workshop, participants will:

- Understand different ways in which qualitative research using focus group and interview methods have been used to support oral health and other health-related studies, and local, state and national health education programs.
- Understand more deeply some of the primary components of a qualitative research plan, particularly important issues that institutional review boards may not require be addressed in advance, and therefore, can be overlooked or undervalued. In particular, the presenters cover various aspects of defining the participant audience for focus groups and interviews to support research goals, developing screening criteria and instruments and methods for recruiting participants, deciding where to conduct the research, developing an engaging and productive group or interview guide, "deep listening" moderating and interviewing priorities, keeping track of data, common reporting options for simple qualitative studies and dilemmas and basic concepts in qualitative analysis.
- Know about professional resources and literature to support qualitative research for a variety of purposes.

Workshop Content: During the workshop, the presenters will use a combination of lecture, slides, demonstrations and audience participation activities to:

1. Highlight examples of their own and others' use of focus groups and interviews for oral health and other health topics to demonstrate varied use of these methodologies and the information they generate. Topics include assessing target audience knowledge, awareness, and beliefs about preventing tooth decay and oral cancer in Maryland, gauging response to messages and materials about these and other health topics, including examples from national women's health education and social marketing programs by the Centers for Disease Control and Prevention and the National Institutes of Health and pretesting survey instruments before they are fully developed and fielded.
2. Discuss the components of a research plan for focus groups and interviews, with a particular emphasis on some of the overlooked or undervalued aspects of executing research plan components, including:
   a. Defining and recruiting participants for basic focus group and interview research: You are interested in learning about low income parents' awareness of tooth decay and how to prevent it to inform the development of messages and materials to prevent tooth decay. What do you consider in defining and locating appropriate participants? The presenters will discuss various means, including building partnerships for outreach, such as with local health departments, non-government organizations (NGOs) in communities and contracting with market research companies and qualitative research consultants. They will address concerns about culturally appropriate screening criteria and recruiting methodologies that will both identify qualified participants and help to discourage "no-shows" and low engagement. Issues and options for providing honoraria for research participants are also covered.
   b. Choosing a setting and "setting the stage" for participants: Where and how do you talk

with and/or observe participants? The presenters discuss considerations for appropriate and convenient settings (in terms of location, transportation and myriad other details for different types of participants) and creating a comfortable atmosphere for research participants, including the advantages and disadvantages of professional focus group facilities, community locations, people's offices, homes, on conference calls or online. Logistical issues such as refreshments are covered, especially for oral health and other health care-related research studies given nutrition, cultural and allergy considerations.

c. Developing a focus group or interview guide and choosing a moderator or interviewer: Why are qualitative instruments called guides? And is the answer important for productive, and useable, data collection? The main elements of the interview guide and types of common questions are covered, with an explanation of critical techniques for putting participants at ease – with the moderator or interviewer, the research topic and questions (e.g., tone, semantics, language, activities), with each other, the presence of recordings and observers – to help to encourage honest, in-depth input. It matters.

   The advantages and caveats of conducting your own groups, or having students conduct groups or interviews are discussed, as well as understanding the types of services that professional qualitative moderators and interviewers offer. What kind of professional and personal background do these research professionals have? What should you look for? Does personality matter? What about language/culture/race/ethnicity/gender? How much do external consulting resources typically cost in 2011? Where do you find these resources, especially for academic research?

d. Data records, common reporting formats and dealing with qualitative data: What are the options and caveats for keeping track of qualitative data? The presenters will discuss audio and video recordings, inviting and training observers and utilizing their field notes, and guidelines for transcribing qualitative research. How do you analyze qualitative information? Can you? The presenters will highlight some of the challenges and basic concepts and products widely discussed today as qualitative research becomes more popular: content analysis, grounded theory, phenomenology, Social Cognitive Theory and other tools, such as NUDIST software. Examples of qualitative studies published in peer reviewed journals in different fields are noted, including some featuring oral health studies utilizing only notes-based analyses and themes.

3. Provide participants with opportunities to discuss and debate different aspects of qualitative techniques based on their own experience and research interests, and to ask the presenters questions.
4. Share a wide range of literature and resources regarding qualitative research, professional resources sensitive to the needs of academic researchers as peer-reviewed publications increase openness to qualitative studies and selected published articles from qualitative studies of possible interest to dental hygiene researchers.

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Osteonecrosis of the Jaw and Oral Hygiene: A Case-Control Study from Condor Dental PBRN

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Presented by: Philippe Hujoel, PhD, DDS, MSD, MS

Introduction: The exposure of dead necrotic bone in the oral cavity is commonly referred as OsteoNecrosis of the Jaw (ONJ). Some known causes of ONJ include exposure to radiation, ingestion of radioactive elements such as radium, exposure to phosphorus or intake of intravenous or oral bisphosphonate medications. It is unclear what factors may prevent ONJ if either medical or environmental exposure is unavoidable.

Oral hygiene was suggested as effective ONJ prevention in the 19th century when the industrial fabrication of matches became associated with a first wave of ONJ cases.[1] The hypothesis that "clean teeth do not decay" was popular in those days. The specific recommendations were to clean the teeth with a small toothbrush with stiff bristles at least once a day with powder (soap with precipitated chalk). Rinsing after each meal and avoiding potential traumatic injury to the teeth (for instance, by eating nuts) was also recommended.[2]

The recommendation to practice good oral hygiene has survived the centuries. An expert panel convened by Novartis Pharmaceuticals Corporation reported that for the prevention of ONJ, "patients should be educated on maintaining excellent oral hygiene to reduce the risk of infection."[3] Similarly, the American Dental Association reported that good oral hygiene is the best way to lower the risk for ONJ.[4] To our knowledge, no controlled evidence is available to determine whether oral hygiene is an effective preventive method.

We briefly report here on some preliminary findings of a nationwide case-control study on the etiology of ONJ as it relates to the role of oral hygiene. Three Practice Based Research Networks (PBRNs) funded by the National Institute of Dental and Craniofacial Research designed a common protocol for a case-control study of ONJ.[5] This case-control study collected data on oral hygiene to determine its relationship to subsequent ONJ risk. Information on brushing, flossing and rinsing approximately 5 years before the onset of ONJ was collected. The question on the use of oral rinses was not specific with respect to the ingredients or active agents. A total of 191 cases and 573 controls formed the basis for the primary analyses. In univariate analyses, there was no significant association between brushing, flossing, or the use of oral rinses with ONJ. Patients reporting to brush once or more than 1 time per day versus those reporting not to brush once a day did not have a lowered ONJ risk (OR = 0.84, p-value = 0.69). Patients reporting to floss once or more per day had no reduced odds for ONJ when compared to those not reporting to floss once a day (R=0.9, p-value=0.56). Finally, no association was present between the use of oral rinses and ONJ. When comparing those individuals that rinsed 4 or more times a week versus those reporting to rinse 3 or fewer days a week, the odds ratio was 0.95 (p-value=0.82). After adjustment for confounding variables, no association could be identified between oral hygiene procedures and the prevention of ONJ.

In conclusion, these exploratory findings in this case-control study could not find evidence that oral hygiene plays a role in the prevention of the onset of ONJ. The potential bias associated with recollecting oral hygiene habits is an important weakness of these presented data. Future studies could collect information on oral hygiene habits to either confirm or refute these first evidence-based data on oral hygiene and ONJ prevention.

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*Collaboration on Networked Dental and Oral Health Research consists of members of PEARL (Practitioners Engaged in Applied Research and Learning, http://pub.emmes.com/study/pearl/), Northwest PRECEDENT (Practice-based REsearch Collaborative in Evidence-based DENTistry, www.nwprecedent.net), and DPBRN (Dental Practice Based Research Network, http://www.dentalpbrn.org/users/publications/collaborativegroup.asp).

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Dental Practice Implementation of a Point of Care Electronic Referral System for Patients Who Smoke: A Dental PBRN Study

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Presented by: Judith Huff-Shack, BS, RDH[1]

Background: Tobacco use is the leading preventable cause of death in the U.S. and has been called the number one behavioral health problem. Although 1 in every 5 Americans smoke cigarettes, approximately 70% report that they want to quit smoking. There are many public health self-management interventions for smoking cessation that have been found to be effective; however, they are substantially underutilized. As more than half of smokers see a dentist at least once per year, patient referrals at point of care to a self-managed smoking cessation intervention could greatly increase their use.

Methods: We conducted a randomized controlled trial with community-based dental practices testing point-of care referrals of smokers to an interactive, tailored patient education website. Intervention practices referred patients via an electronic referral system (ReferASmoker) and control practices referred patients via a paper-based information prescription. Both control and intervention practices had access to the ReferASmoker website that has resources to assist with tobacco cessation services. The intervention practices, but not the control practices, received feedback about their number of patient referrals and the referral numbers of their peers.

Results: One hundred and one community-based dental practices from 8 states referred close to 1,900 patients to a patient education website for the self-management of smoking cessation. Based on estimates by the dental practices, the majority of patients were between the ages of 19 and 64 years, 23% of patients seen in participating practices were African American and 61% of practices saw patients with private insurance. Control and intervention practices were similar at baseline on all characteristics assessed except control practices had a higher self-reported proportion of African American patients. Based on the project coordinator comments, the ReferASmoker website was easy to use and offered useful resources to assist with tobacco control services.

Conclusions: Providers actively engaged in the program and were willing to refer patients to an online, tailored patient education website. Dental practices found the ReferASmoker tool useful and easy to implement into practice.

1The DPBRN Collaborative Group comprises practitioners, faculty and staff who contributed to this DPBRN activity. A list of these persons is at http://www.dpbrn.org/users/publications/Default.aspx

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Current Evidence For Remineralizing Therapeutics In Caries Management

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Despite years of research directed at understanding the causes of dental caries and the development of preventive therapeutics for the management of dental caries, the population continues to have a substantial burden of disease. Dental caries afflicts almost the entire population by adulthood and is the most common chronic disease of childhood surpassing asthma and other common pathologies.[1] Thus the need to advance our understanding of the dental caries disease process and more effective intervention approaches remains an important undertaking. Traditional approaches to caries management include mechanical plaque control, diet modification, fluorides, antimicrobial agents, sealants and non-fluoride remineralizing therapies. The purpose of this manuscript is to briefly present our current knowledge of this latter group of therapeutics.

The caries process involves an imbalance of acid attack from the metabolic products of oral microbes during carbohydrate consumption and remineralization when the salivary pH becomes more basic and the enamel can take up new calcium and phosphate minerals to replace those lost during demineralization.[2] Saliva is a critical requisite for this process to occur. Its buffering and aqueous properties allow it to help neutralize the acids in the oral cavity and to provide the vehicle necessary to deliver critical ions to the tooth surface and to penetrate into the body of the carious lesion. Fluoride products have long been known to enhance the remineralization process and reduce caries in the population through a variety of different delivery systems.[3] Fluoride ions are highly reactive and when present in the oral cavity they will interact with partially demineralized enamel crystallites and then attract and react with calcium and phosphate ions available through the saliva and thereby stimulate remineralization. A variety of products are now commercially available that are directed at helping control dental caries by stimulating salivary production, neutralizing the biofilm pH and/or by enhancing remineralization by supplying bioavailable calcium and phosphate ions.[4] These products can be grouped into several different categories, but there can be overlap with some products using several or all of the above mentioned approaches.

Stimulating salivary flow helps reduce the risk of dental caries. This is accomplished primarily through the use of chewing gums and lozenges. There have been numerous clinical studies on the effect of chewing gum on dental caries. Gums with artificial sweeteners when chewed for 10 to 20 minutes 3 to 6 times per day results in reduction in caries compared with control groups that did not chew gum. These types of studies have been completed primarily in children and show a reduction of caries predominantly on proximal surfaces. There are several different polyol sweeteners used in gums and lozenges. There is evidence that gums with xylitol provide great caries reductions compared with sorbitol or combinations of polyols. There is currently no clinical evidence that the addition of xylitol to toothpaste or dental rinses is of any benefit in the management of dental caries.[4]

The ideal remineralizing agent will provide adequate amounts of calcium and phosphate ions to the body of the carious lesion where they are needed and will not readily precipitate on the tooth surface or increase calculus formation. A variety of compounds are currently available that are directed at fulfilling these requirements, including amorphous calcium phosphate (ACP), calcium sodium phosphosilicate and tricalcium phosphate. Most of these agents are used primarily in combination with other compounds or with fluorides and are available in toothpastes, fluoride varnishes and chewing gums. Many of these commercially available products have little or no clinical data to support their effectiveness. The most clinical data exists for ACP products and primarily in the ACP complexes that are available in some chewing gums. There is currently no clinical data showing an increased effectiveness over fluoride alone when ACP, tricalcium phosphate or calcium sodium phosphosilicate are added to fluoride varnish.[4,5] There is in-vitro data and, for some products, substantial in-situ data indicating that the addition of these remineralizing compounds can be effective.

Phosphorylated salivary proteins such as statherin are known to help enhance mineral delivery to the tooth surface and provide protection against dental caries. Research on other phosphorylated proteins, such as the milk casein phosphopeptides (CPP), suggests they could also have protective properties. These phosphorylated proteins can help bring the ions that are critical for optimal remineralization to the necessary location of the tooth surface and demineralization site. There are a number of products now available using CPP that is complexed with ACP (CPP–ACP) to enhance remineralization. The CPP-ACP complex is most commonly used in chewing gums and in a topical foam or tooth moose. The in-situ data shows the CPP-ACP complex will enhance remineralization with and without fluoride. Clinical studies are less convincing, with mostly short-term studies on white spot or early non-cavitated lesions being available at this time. Further, clinical studies are necessary to determine if the CPP-ACP products

are effective in preventing clinical caries.

Agents that modify oral pH and antimicrobial agents also are commercially available for caries management. Mouthrinse is now available with sodium hypochlorite (0.2% concentration), which is one of the most common disinfecting and bleaching agents used around the world. It also is very basic and might thus assist in neutralizing an acidic oral biofilm. The antimicrobial agent chlorhexidene is available in an oral rinse, and in the U.S. is available in a concentration of 0.12%. Other antimicrobial agents directed at controlling caries include a chlorhexidene and thymol varnish. The clinical evidence available at this time indicates that the chlorhexidene mouthrinse is not effective against dental caries, and there is no data as to additional caries prevention benefit by adding 0.2% sodium hypochlorite to a mouthrinse. There is some clinical evidence that a chlorhexidene/thymol varnish could be effective in reducing root caries in an adult population, but there is inadequate clinical data that it is effective for preventing caries in children. There are a number of products undergoing testing that will add to our knowledge of how these and new products can be used to help manage dental caries in our patient populations.

Are there risks involved with the use of any of these products? Most therapeutic agents will have some risks of adverse reactions, but for most the risks appear minimal. The elements and ions in the different remineralizing complexes are ubiquitous in the environment and quite safe if not consumed excessively. Chewing gum is not recommended for children under 4 years of age as it represents a potential choking hazard. Milk-derived peptides used in the CPP-ACP products are not recommended for individuals with a known milk allergy. Increased consumption of artificial sweeteners is associated with an increased risk of obesity and diabetes.

Incorporating caries control regimes is predicated on establishing an individual's risk for developing dental caries. There are a number of caries risk assessment tools available (e.g. American Dental Association, American Academy of Pediatric Dentistry, CAMBRA, Cariogram), all using a variety of indicators to determine an individual's risk. There is no evidence that one system is inherently superior to others, but it is critical that clinicians evaluate as objectively as possible their patients' caries risk status. Indicators such as previous dental caries, fluoride exposure, presence of enamel defects, salivary flow and consistency and dietary habits, as well as many other factors, are known to be predictive of caries risk and are thus represented in all of these caries risk assessment approaches. The current evidence shows that fluoride products are the most effective remineralizing agents. In individuals with disease that is not being controlled through more conventional approaches (e.g. hygiene, diet, fluorides, etc.), then adjunctive remineralizing approaches might be of benefit, although the clinical data to support their use is generally lacking. Some of these products could potentially be of benefit for patients who do not want to or who will not comply with prescribed fluoride therapies.

The management of dental caries remains an evolving science with new knowledge regarding the etiology of the disease, new predictive tools and new therapeutics continuing to change the landscape for the diagnosis and treatment of this highly prevalent disease. There is little question that the clinician should carefully assess each patient's risk for developing dental caries and then direct their preventive and therapeutic interventions in a targeted manner. Understanding that dental caries is an infectious and preventable disease provides the opportunity for oral health care providers to turn the tide on the dental caries epidemic by using their diagnostic skills and then selectively applying appropriate therapies directed at specific aspects of the dental caries disease process. There are numerous new agents on the market and promising new therapeutic approaches on the horizon. Clinicians are and will continue to be challenged with discerning how these agents work and the evidence to support their application in the clinical setting.

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CAMBRA: Development and Incorporation into a Dental Hygiene Program

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Caries Management by Risk Assessment (CAMBRA) is becoming the standard of care in the delivery of patient care. CAMBRA is a program for managing dental decay by assessing the patient's risk category and level of caries activity to determine the most effective treatment strategies. Dental caries is treated as an infectious disease that is curable and preventable. Emphasis is on changing the behavior and attitude of patients so that they take an active role in the management of their dental decay.

With 30 years of scientific research on dental caries, Dr. John Featherstone, along with colleagues, laid the foundation for the CAMBRA guidelines and protocols.[1–3] The first guidelines were published in 2003 and are continually being evaluated and revised.[4] A Western CAMBRA Coalition was initiated in 2002 for the purpose of exchanging information about how to incorporate CAMBRA into teaching and clinical practice with representatives from 5 California schools.[5] The Coalition is continually growing to include representatives from schools across the nation, the dental products industry, the dental insurance industry, government and state licensing boards, dental research and clinical practice.

Recently, a practice-based research project for CAMBRA has been initiated. This project will begin in 2011 with a network of 17 dentists who have been calibrated on the CAMBRA guidelines and protocols. The purpose is to measure patient and provider acceptance of incorporating CAMBRA into clinical practice. The ultimate goal is to gather data to determine if there is scientific evidence to support CAMBRA as the standard of care.

Incorporating CAMBRA into dental hygiene and dental programs can be beneficial for both patients and students. By learning the scientific rationale and gaining practical clinical experience with CAMBRA, students are prepared to practice CAMBRA upon graduation.

CAMBRA Protocol Development: At the Ostrow School of Dentistry of USC, the Dean requested that CAMBRA be incorporated into the clinical program. First, a committee of 1 dental hygiene and 4 dental faculty members was formed to develop a CAMBRA protocol for use in the dental hygiene and dental program. The committee members individually read the scientific research related to CAMBRA and then met to discuss their findings. In addition, committee members attended various CAMBRA meetings and CAMBRA coalitions. Each member summarized key points that could be used to develop the school's protocol.

The committee members adopted the principle that conventional restorative treatment does little to treat the actual etiology of and risk factors leading to dental caries. The dental school will use CAMBRA to diagnose, treat and prevent dental caries from further developing. The diagnostic goals are to determine the risk level for each patient, the level of caries activity and the frequency of exams, radiographs and treatment strategies.

Once the philosophy and principle of CAMBRA were established, the next steps were to set the guidelines and protocol for incorporation into the curriculum and clinic. This included selecting the risk assessment form, determining the treatment strategies for each risk category, determining the products to be used by the patient at home and in the clinic, setting guidelines for recording the information into the computerized patient record, and guidelines for follow up.

The committee adopted a risk assessment form that is a slight variation of Featherstone's form.[3] The modifications include a different format for recording the risk factors and a very specific outline regarding the treatment strategies. Another form was developed to record patient compliance with treatment strategies. The committee made the decision to provide patients at high and extreme risk categories with a take home kit. This kit consists of 16 ounces of 0.12% chlorhexidine, 4 ounces of 1.1% NaF prescription paste, 120 xylitol gumballs, dental floss and a toothbrush. An instruction sheet is included in the kit. Patients with xerostomia are given a non-alcohol chlorhexidine rinse. For patients who have TMJ problems or inability to chew gum, xylitol mints are offered.

Another essential part of the CAMBRA program was establishing the fee, which was based on the patient population and expense of products. The CAMBRA fee includes the initial risk assessment appointment, a patient home care kit, one fluoride application, oral hygiene instructions, nutritional counseling and the first caries recall exam. Finally, the committee members determined how to educate the students and faculty.

CAMBRA Implementation: Education of the dental hygiene students included the principles and techniques for biofilm removal, nutritional counseling, fluoride and antimicrobial therapy, and patient motivation. This information is already incorporated

into the dental hygiene curriculum in various courses. In addition to these courses, the Dean, who outlined the scientific basis, provided a 1 hour lecture and general guidelines for CAMBRA and three additional hours were presented by a dental hygiene faculty member outlining the specific details of incorporation of CAMBRA into the clinical program. This education included a one-hour laboratory experience on how to conduct saliva tests.

Education of the dental hygiene faculty included 4 hours of education: a 2 hour presentation by the Dean explaining the importance, scientific evidence and an overview of the program's expectations. This was followed by a 2 hour lecture by the dental hygiene faculty committee member explaining the details of incorporating the program into the curriculum and clinic.

In addition to the educational sessions, the protocol for the program is outlined and given to each student and faculty member. Each patient treated in the dental hygiene clinic is assessed and assigned a risk category. The dental hygiene student conducts the initial assessment, which is then reviewed and approved by the faculty member. The information is recorded in the patient's electronic chart.

The following treatment strategies are followed based on the risk assessment level of the patient:

- Low Risk: oral hygiene education, biofilm control, nutritional counseling, and use of a fluoridated dentifrice 1 to 2 times per day
- Moderate Risk: all of the strategies in low risk PLUS using an over-the-counter (OTC) 0.05% NaF rinse daily, xylitol gum or mints (2 pieces 4 times per day for at least 5 minutes) and application of 5% NaF varnish (2 times per year)
- High Risk: oral hygiene education, nutritional counseling, xylitol gum, 0.12% chlorhexidine 1 time per day for 1 minute, 1 week per month, replace OTC dentifrice with a 1.1% NaF prescription dentifrice 2 times per day
- Extreme Risk: same as high risk except use of 0.12% chlorhexidine in water base, a calcium/phosphate paste and products for xerostomia, such as rinses and gels

Additional treatment strategies include saliva testing for the high and extreme high-risk categories. Initially, it was decided only to do pH testing and then eventually incorporate a saliva buffering test and bacterial culturing for use as criteria to determine the success of treatment strategies. Fluoride varnish for the high and extreme risk is recommended 3 to 4 times per year.

When needed, the patient is referred for restorative treatment after home care treatment and instructions have been provided. Radiographs are taken based on the risk assessment level: at 6 months for extreme risk, 12 months for high risk, 18 months for moderate risk and 24 months for low risk.

The goal is to move patients who are in a higher risk category to a lower risk category. Therefore, follow-up care is essential for evaluation of the patient's progress and to encourage patient compliance. For patients in the high or extreme risk category, the follow up includes a 2 to 4 week follow up appointment to evaluate compliance, a 4 month appointment to evaluate compliance and an 8 month caries recall (high risk) or 6 month caries recall (extreme risk).

Incorporating CAMBRA into a dental hygiene program does have its challenges. Key factors to success include support of the Dean, education of the students and faculty, and a patient tracking system. The biggest challenge in our program has been the follow-up care due to lack of follow through appointments with the patients. This problem is due both to patients not keeping the follow-up appointments and to students not scheduling the follow-up appointments. The committee members are meeting on a regular basis to address some of the concerns and determine solutions. Although the scientific evidence for CAMBRA is very compelling, more research on patient compliance and motivation is needed to help insure the success of CAMBRA, especially in the dental school environment.

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