



American  
Dental  
Hygienists'  
Association

# Journal of Dental Hygiene

THE AMERICAN DENTAL HYGIENISTS' ASSOCIATION

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- Evidence-Based Considerations for the Clinical Use of Locally Delivered, Controlled-Release Antimicrobials in Periodontal Therapy
- Strategies for Service-Learning Assessment in Dental Hygiene Education
- Access to Oral Health Care in the Georgia Prison System
- A Qualitative Case Study of the Legislative Process of the Hygienist-Therapist Bill in a Large Midwestern State
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- Public Health Dental Hygiene: An Option for Improved Quality of Care and Quality of Life
- Accuracy of Digital Arm and Wrist Manometers: Clinical Implications for the Dental Hygienist

# Journal of Dental Hygiene

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## STATEMENT OF PURPOSE

The *Journal of Dental Hygiene* is the refereed, scientific publication of the American Dental Hygienists' Association. It promotes the publication of original research related to the profession, the education, and the practice of dental hygiene. The Journal supports the development and dissemination of a dental hygiene body of knowledge through scientific inquiry in basic, applied and clinical research.

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# Editorial

Maria Perno Goldie, RDH, BA, MS



## Dental Hygiene Internationally: The 19th International Symposium on Dental Hygiene

The International Federation of Dental Hygienists (IFDH) is an international, non-governmental, non-profit organization, free from any political, racial or religious ties. It unites dental hygiene associations from around the world in their common cause of promoting dental health. The IFDH was comprised of 23 members prior to the meeting: Australia, Austria, Canada, Denmark, Fiji, Finland, Germany, Ireland, Israel, Italy, Japan, Korea, Latvia, Netherlands, New Zealand, Norway, Portugal, Slovakia, South Africa, Sweden, Switzerland, the United Kingdom and the United States of America. We welcomed 3 new members in Cape Town: Nepal, Spain and Russia.

The 19<sup>th</sup> International Symposium on Dental Hygiene (ISDH) was held August 14 to 17, 2013 in Cape Town, South Africa. The Symposium was co-hosted by the IFDH and the Oral Hygienists' Association of South Africa (OHASA). We celebrated 100 years of dental hygiene, and explored the role of dental hygienists as primary health care providers in total health care. The Scientific Program theme and focus was about how oral health is central to our daily life and well-being, and exerts a fundamental influence on the quality of life for every individual. Both community experience and research evidence support that oral health is more than just the absence of disease or loss of function. People are increasingly aware that the optimal functioning of the oral-facial structures is important in their comfort and well-being and for preserving their self-esteem. Individuals and communities have to be educated regarding the causes of oral diseases and how they can be involved in preventing or eliminating such diseases. They can be informed through outreach, health education and health promotion.

The World Dental Hygienist Award 2013 winners were honored at the meeting. The generous support of SUNSTAR has provided the foundation for the prestigious World Dental Hygienist Award. Congratulations to the 2013 recipients:

- Research category - Ms D.E. Slot, "The Effect of 1% Chlorhexidine Gel and 0.12% Dentifrice

Gel on Plaque Accumulation: A Three Day Non-Brushing Model"

- Project category - Mr M. Rui Araújo, "An Inclusive Public Dental Health Project in Portugal"
- Student Research category - Mr T. Blom, "The Effect of Mouth Rinses on Oral Malodour: A Systematic Review"

All recipients presented their papers during the 2013 International Symposium on Dental Hygiene.

As I traveled the world the last 3 years as the 2010 to 2013 President of the IFDH, I realized that there is no global standard for dental hygiene education. As countries begin to recognize dental hygiene as a profession, we see the number of years of education required increasing. The Netherlands is the highest with a 4 year minimum requirement. Patricia Johnson conducted an international longitudinal study that examines trends and changes in dental hygiene.<sup>1</sup> Over the 19 year period, there was a noticeable increase in supply accompanied by improved dental hygienist-to-population and to-dentist ratios, continuing high workforce participation rates, shift to and increase in the number of baccalaureate-level education programs, and increase in scope of practice and professional autonomy including, for many countries, a decline in mandatory work supervision and slight increase in independent practice.<sup>1</sup>

By far the greatest increase in the number of dental hygienists was observed in Italy, a notable 2,207.7% over the 18 year period between 1987 to 2005.<sup>1</sup> Additional information on dental hygiene in Italy was presented to the Belgian Society of Periodontology.<sup>2</sup> Italy also has a national research association/society called the Italian Society of Oral Hygiene Sciences (La Società Italiana di Scienze dell'Igiene Orale (SISIO)). SISIO objectives are to accelerate the development of oral hygiene research, create a research infrastructure to serve the profession and build a solid scientific basis for the clinical practice of oral hygiene. They strive for the cultural and scientific growth of dental hygiene. The

SISIO slogan is: Learn about the science of oral hygiene and how to be protagonists (translated loosely to mean learn to be proactive and be major players in the field of prevention). SISIO will not replace the professional associations, like Associazione Igienisti Dentali Italiani (AIDI), but will operate on a purely scientific and cultural basis, in synergy and harmony with the professional organizations.

In Europe, we see The Bologna Process. The Bologna Process launched the European Higher Education Area in 2010, in which students can choose from a wide and transparent range of high quality courses and benefit from smooth recognition procedures.<sup>3</sup> The Bologna Declaration of June 1999 put in motion a series of reforms needed to make European Higher Education more compatible and comparable, more competitive and more attractive for

Europeans and for students and scholars from other continents. Reform was needed then and reform is still needed today if Europe is to match the performance of the best performing systems in the world. For more specifically on dental hygiene education in Europe, see the article by Luciak-Donsberger and Eaton.<sup>4</sup>

The Swiss Dental Hygienists will, for the first time, welcome the IFDH and dental hygienists from around the world for the 2016 ISDH. Held at Basel Switzerland, the meeting will be held June 23 to 25, 2016, and the theme for the meeting is: Dental Hygiene – New Challenges. For more information, visit the website.<sup>5</sup> I hope to see you all there!

Sincerely,  
Maria Perno Goldie, RDH, BA, MS

## References

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1. Johnson PM. International profiles of dental hygiene 1987 to 2006: a 21-nation comparative study. *Int Dent J*. 2009;59(2):63-77.
2. Marchisio O. Dental hygienists in Italy: Where are we? *Dentistry IQ* [Internet]. 2013 March 1. Available from: <http://www.dentistryiq.com/articles/2013/03/dental-hygienists-in-italy.html>
3. The Bologna Process - Towards the European Higher Education Area. European Commission [Internet]. 2013 July 9. Available from: [http://ec.europa.eu/education/higher-education/bologna\\_en.htm](http://ec.europa.eu/education/higher-education/bologna_en.htm)
4. Luciak-Donsberger C, Eaton KA. Dental hygienists in Europe: trends towards harmonization of education and practice since 2003. *Int J Dent Hyg*. 2009;7(4):273-284.
5. Dental Hygiene – New Challenges. Swiss Dental Hygienists [Internet]. Available from: <http://isdh2016.dentalhygienists.ch/>

# Literature Review

## Evidence-Based Considerations for the Clinical Use of Locally Delivered, Controlled-Release Antimicrobials in Periodontal Therapy

Richard D. Finkelman, DDS, PhD; Alan M. Polson, DMD, MS

### Introduction

The technologies for the clinical use in dentistry of locally delivered, controlled-release antimicrobials, both antibiotic and antiseptic formulations, have been available for more than a decade, but their routine incorporation in clinical practice for patient treatment has been slow despite the recognition of the bacterial initiation of periodontal disease, that the efficacy of scaling and root planing (SRP) or other mechanical therapy generally is a consequence of either a reduction of the bacterial load or an alteration of the composition of the bacterial flora at the gingival or periodontal site, and that the antibacterial effect of mechanical treatment alone is less than complete. It would therefore seem intuitive that the clinician should desire to augment chemically the antibacterial effect of mechanical therapy.

Four locally delivered, controlled-release antimicrobial products have been developed for use in dentistry in the U.S. based on 4 different antimicrobials: tetracycline (TET) fiber, chlorhexidine (CHX) chip, doxycycline (DOX) gel, and minocycline (MIN) microspheres.<sup>1-4</sup> The TET fiber was the first product introduced to the U.S. market and was the prototypic system. Although the TET fiber is no longer available in the U.S., it is included in this discussion because the data generated from studies of the TET fiber are pertinent for a discussion of the general effects of locally delivered, controlled-release antimicrobials. The effects of locally delivered, controlled-release antimicrobials are considered as a drug class rather than individually. Since appropriate comparative trials have not been performed, there are insufficient data on which to base any comparison of agents or to consider differential indications for use. The

### Abstract

**Purpose:** Locally delivered, controlled-release antimicrobials have long been available in dentistry. Their utilization in routine clinical practice, however, has been slow, perhaps because of concerns about clinical benefits or costs or possibly due to a lack of understanding of their efficacy or proper use. In this paper the evidence regarding locally delivered, controlled-released antimicrobials is considered, and some of the controversies surrounding these agents are discussed. Evidence-based considerations regarding their use are also summarized. Scaling and root planing (SRP) procedures are the backbone of non-surgical periodontal therapy. Since a number of well designed clinical trials have demonstrated that adjunctive, locally delivered, controlled-release antimicrobials make SRP significantly more effective to reduce clinical signs of chronic periodontitis with a known safety profile, and since SRP procedures have previously been considered the standard of care for non-surgical periodontal therapy, a case is made that SRP in combination with adjunctive therapy, administered in a manner consistent with the approved full prescribing information, could be considered a new standard.

**Keywords:** antimicrobials, clinical trials, controlled-release, local delivery, periodontitis

This study supports the NDHRA priority area, **Clinical Dental Hygiene Care:** Assess the use of evidence-based treatment recommendations in dental hygiene practice.

indications for use for each product can only be based on the indications as noted in the respective full prescribing information.

The appropriate clinical use of locally delivered, controlled-release antimicrobials has been the subject of some controversy, perhaps at least partly fostered by comments and recommendations in position papers that were published shortly after the introduction of these agents into the U.S. market, recommendations published even though a number of them seemed to be based on clinical opinions and not well supported by research data.<sup>5,6</sup> The positions were subsequently supported by other reports,<sup>7-9</sup> although concerns regarding these positions have also been published.<sup>10,11</sup>

It has been well accepted that optimal patient

care should be evidence-based.<sup>12,13</sup> Thus, it is appropriate in this review to revisit the clinical evidence regarding locally delivered, controlled-release antimicrobials. A discussion of perceived controversies and previously published concerns is also needed. This review has been limited mainly to studies with Phase III designs, since these represent the strongest clinical evidence available for the purpose of clinical decision making and are typically the studies on which regulatory decisions are based. Other studies (e.g., Phase I, Phase II) are usually more exploratory in nature to give initial information regarding drug compounds, including preliminary safety or efficacy or to explore doses, but are not sufficiently adequate or well-controlled to provide conclusive data regarding either efficacy or safety. Other studies, although perhaps of high quality to give preliminary information, cannot provide data on which to base clinical decisions. The U.S. Food and Drug Administration (FDA) website notes the common characteristics of study designs that are considered adequate and well-controlled (Table I).<sup>14</sup> Comments regarding less robust studies are included as appropriate, although this discussion was not intended to be a systematic review of the literature. The purpose of this paper is to consider existing clinical evidence for the use of these agents and follow with an evidence-based consideration of the appropriate use of locally delivered, controlled-release antimicrobials for patient treatment. Included is a discussion of treatment outcomes, clinical significance and the value of these agents versus other available local therapies, including irrigation.

### Previously Published Positions

The position papers<sup>5,6</sup> and review<sup>7</sup> cited above suggested that the best place to use locally delivered, controlled-release antimicrobials may be at the periodontal site that has not responded to other treatment, essentially recommending that these agents need not be used until other therapy has failed. Supportive evidence for this view is lacking, however, since adequate comparative data from responding versus non-responding sites are not available. Thus, the recommendation seems to be based on opinion rather than evidence, a conclusion also reached at a symposium sponsored by the Oral Health Research Group, co-sponsored by the Periodontal Research Group, at the 2001 Annual Meeting of the American Association for Dental Research (AADR) to consider the clinical significance of non-surgical periodontal therapy.<sup>15</sup> Other reports, however, do support the efficacy of locally delivered, controlled-release antimicrobials in persistent pockets or in

Table I: Characteristics of Adequate and Well-Controlled (Phase III) Clinical Trial Designs\*

1. Type I error rate control
2. Clear statement of the objectives, proposed and actual
3. Methods of analysis in the protocol, statistical analysis plan and reports
4. Methods of adequate assurance of patient selections
5. Patient assignments that minimize bias, group comparability
6. Methods to minimize bias for all parties: patients, investigators, and data analysts
7. Endpoints well-defined and address the primary hypothesis
8. Analysis of results allows for the interpretability of the effects of the study drug

\*Adapted from US Food and Drug Administration 21CFR314.126<sup>14</sup>

non-responding sites as an alternative to further SRP or perhaps to surgical treatment, although a lack of additional benefit in non-responding sites has also been reported.<sup>16-18</sup>

The Research, Science and Therapy Committee of the American Academy of Periodontology has published that they "strongly feel that mechanical instrumentation can usually achieve the same result as local delivery when administered as a monotherapy or when it is used as an adjunct to treatment."<sup>19</sup> However, no supportive data were referenced, especially regarding the adjunctive use of local delivery. The literature suggests otherwise, that locally delivered, controlled-release antimicrobials significantly augment the efficacy of SRP. Multiple clinical trials have consistently shown, in at least 6 multi-centered, randomized, Phase III-style trials, that SRP plus adjunctive treatment resulted in significantly greater efficacy, as measured by probing depth reduction, compared with SRP alone.<sup>2,4,20-22</sup> Probing depth is thought to be a clinically meaningful endpoint for periodontitis trials, an appropriate outcome measure of inflammation and predictive of further disease progression, although the progression of periodontitis may be most meaningfully measured by loss of attachment or alveolar bone.<sup>23-31</sup>

The efficacy of local adjuncts was subsequently supported in 2003 by an international workshop, which also concluded that the clinical result obtained following SRP that includes the adjunctive use of a locally delivered, controlled-release anti-

microbial is significantly enhanced in comparison with that following SRP alone.<sup>32</sup> The conclusion was based on data derived from multiple randomized clinical trials, long recognized as the strongest and most compelling evidence on which to base clinical treatment.<sup>12,13,33</sup>

### Clinical Significance

The mean differences in clinical trials between the probing depth reduction from baseline between treated groups (SRP plus adjunctive agent) and control (SRP plus placebo or SRP alone) were reported in terms of tenths of a millimeter (approximately 0.2 to 0.7 mm).<sup>2,4,20-22</sup> The changes numerically seem small and of little clinical significance, but they need to be viewed from a number of perspectives. For example, it is commonly believed that only a low percentage of periodontal sites are "active," i.e., actively evidencing tissue breakdown, and that most sites are relatively stable and "inactive."<sup>27,34-36</sup> Since most sites may be stable at most times, it might be anticipated that, in a clinical trial of all patients and all periodontal sites, unless it is a trial which is specifically enriched for "active" sites, there may not be much difference between treated and control in most patients. In other words, many of the data points used to define a mean difference may be small or near zero (i.e., no difference versus the control group, SRP alone). In addition, clinical trials for FDA registration are typically performed using an intent-to-treat analysis. All entered patients are included in the analysis whether they finish the trial or not, therefore, the expected small mean changes may be even further diluted by data recorded prior to the planned endpoint. The trials that have been cited included data from subjects who did not complete the trials per protocol and for whom treatment was incomplete. It would have thus been expected that the outcome as mean changes would be small, further highlighting the importance of the statistical analyses of the changes. Adjunctive locally delivered, controlled-release antimicrobials have consistently shown this statistical benefit in multiple, well designed clinical trials, for example, improving mean probing depth reduction across all tested sites entered, including those patients with incomplete treatment, in a number of trials approximately from 22% to 68% compared with control (Table II), a change that certainly seems clinically significant. A significant mean percentage change versus control implies that the response curve is significantly shifted toward increased benefit for the population under study.

Perhaps the most compelling evidence to sup-

port clinical significance comes from the consideration of large changes. A probing depth reduction of 2 mm or greater from baseline is commonly considered evidence of clinical significance.<sup>2,4,37</sup> The adjunctive use of locally delivered, controlled-release antimicrobials resulted in a significantly greater proportion of patients or sites with a probing depth reduction from baseline of 2 mm or more in comparison with SRP alone (Table II). This level of reduction may ultimately translate into a clinical outcome of fewer lost teeth, but this hypothesis remains to be tested in clinical trials with tooth mortality as the primary objective rather than surrogate endpoints.<sup>38</sup> Thus, the data support that adjunctive therapy is not only statistically significant but clinically significant as well. The clinical significance of the adjunctive benefit was also acknowledged at a symposium to consider locally delivered chemotherapeutic agents in periodontal therapy sponsored by the Periodontal Research Group at the 1998 Annual Meeting of the AADR.<sup>39</sup>

To consider the results from another perspective, surgery is a common treatment for patients with periodontal pockets, but the mean differences in probing depth reduction between sites treated surgically versus sites treated with SRP alone is also in the neighborhood of several tenths of a millimeter.<sup>40,41</sup> If a mean change of tenths of a millimeter is not clinically significant, then it could be questioned whether any patient prospectively ever really needs any periodontal treatment beyond SRP. This conclusion has been supported by the published suggestion that continued non-surgical therapy usually provides a mean probing depth reduction of 2 mm or greater.<sup>19</sup> With respect to periodontal surgery, the 1996 World Workshop in Periodontics concluded that "[o]utcomes [following both surgical and non-surgical therapy] after several years are generally similar."<sup>42</sup>

Further, with respect to a potential comparison with surgical outcomes, it has been suggested verbally, starting as early as 1993 (Killooy WJ, personal communication, 2002), and in print in 1998, that adjunctive locally delivered, controlled-release antimicrobials may improve outcomes following regenerative periodontal surgery.<sup>43,44</sup> In a pilot clinical trial, the adjunctive use of CHX chip with regenerative surgery resulted in more than a 100% greater mean improvement from baseline in bone height and mass 9 months after surgical treatment compared with SRP alone and surgery.<sup>45</sup> Interestingly, both groups had also received prophylactic systemic antimicrobial treatment as well prior to surgery (mostly cephalexin).



Table II: Summary of locally delivered, controlled-release antimicrobials with SRP

Agent	Use	Study Duration	Mean PD Outcome	Numbers or Proportions of Sites or Sites Per Patient Evidencing a PD Reduction $\geq 2$ mm from Baseline	Reference
Minocycline microspheres	Adjunctive	9 months	<ul style="list-style-type: none"> <li>• 22% greater reduction vs SRP alone</li> <li>• 32% greater reduction vs SRP + vehicle (both <math>p &lt; 0.001</math>)</li> </ul>	<ul style="list-style-type: none"> <li>• 23% increase vs SRP alone</li> <li>• 40% increase vs SRP + vehicle (both <math>p &lt; 0.001</math>)</li> </ul>	4
Doxycycline gel	Monotherapy	9 months	<p>Study 1</p> <ul style="list-style-type: none"> <li>• 22% greater reduction vs SRP alone (<math>p = 0.05</math>)</li> <li>• 37% greater reduction vs vehicle (<math>p = 0.001</math>)</li> <li>• 120% greater reduction vs OH alone (<math>p &lt; 0.001</math>)</li> </ul> <p>Study 2</p> <ul style="list-style-type: none"> <li>• No difference vs SRP alone (<math>p = 0.765</math>)</li> <li>• 30% greater reduction vs vehicle (<math>p = 0.001</math>)</li> <li>• 40% greater reduction vs OH alone (<math>p &lt; 0.001</math>)</li> </ul>	<p>Study 1</p> <ul style="list-style-type: none"> <li>• 3% increase vs SRP alone</li> <li>• 45% increase vs vehicle</li> <li>• 113% increase vs OH alone</li> </ul> <p>Study 2</p> <ul style="list-style-type: none"> <li>• 4.7% decrease vs SRP alone</li> <li>• 52% increase vs vehicle</li> <li>• 78% increase vs OH alone (statistical analysis of PD reduction <math>\geq 2</math> mm not reported)</li> </ul>	3
Chlorhexidine chip*	Adjunctive	9 months	<ul style="list-style-type: none"> <li>• 46% greater reduction vs SRP alone (<math>p = 0.00001</math>)</li> <li>• 38% greater reduction vs SRP + vehicle (<math>p = 0.00056</math>)</li> </ul>	<ul style="list-style-type: none"> <li>• 139% increase vs SRP alone (<math>p &lt; 0.0001</math>)</li> <li>• 48% increase vs SRP + vehicle (<math>p = 0.039</math>)</li> </ul>	2
Chlorhexidine chip	Adjunctive	6 months	<ul style="list-style-type: none"> <li>• 66% greater reduction vs SRP alone (<math>p \leq 0.0001</math>)</li> </ul>	<ul style="list-style-type: none"> <li>• 66% increase vs SRP alone (<math>p \leq 0.0001</math>)</li> </ul>	22
Chlorhexidine chip	Adjunctive	6 months	<ul style="list-style-type: none"> <li>• Approximately 50% greater reduction vs SRP alone (<math>p &lt; 0.001</math>)</li> </ul>	<ul style="list-style-type: none"> <li>• 113% increase vs SRP alone (<math>p &lt; 0.01</math>)</li> </ul>	21
Tetracycline fiber	Adjunctive	6 months	<ul style="list-style-type: none"> <li>• 68% greater reduction vs SRP alone (<math>p &lt; 0.01</math>)</li> </ul>	<ul style="list-style-type: none"> <li>• Not reported</li> </ul>	20
Tetracycline fiber	Monotherapy	60 days	<ul style="list-style-type: none"> <li>• 42% greater reduction vs SRP alone (<math>p = 0.0002</math>)</li> <li>• 67% greater reduction vs control fiber (<math>p = 0.0001</math>)</li> <li>• 133% greater reduction vs no treatment (<math>p = 0.0001</math>)</li> </ul>	<ul style="list-style-type: none"> <li>• Not reported</li> </ul>	1

SRP, scaling and root planing; PD, probing depth; OH, oral hygiene. \*Pooled data from 2 studies

Other reports support the lack of efficacy of systemic antimicrobials and the benefit of locally delivered antimicrobials as adjunctive treatments in the regenerative setting.<sup>46,47</sup> If confirmed by subsequent trials, the collective data could sup-

port the use of this intervention to enhance outcomes of regenerative periodontal procedures. Additionally, Aichelmann-Reidy and coworkers have suggested that regenerative surgical procedures should include an adjunctive locally de-

livered, controlled-release antimicrobial agent in order to provide a more consistent clinical benefit (e.g., improved regeneration).<sup>48</sup> However, this hypothesis remains to be tested in prospective trials.

Potentially even more important for a greater number of patients, in a subset of patients from the CHX chip clinical trials, some patients treated with SRP alone lost bone over 9 months as measured by subtraction radiography, but no patient treated adjunctively showed any radiographic evidence of bone loss.<sup>49</sup> Adequate and well-controlled clinical trials are needed to test the hypothesis that adjunctive, locally delivered controlled-release antimicrobials may reduce radiographic bone loss.

### **Adjunctive Therapy and Cigarette Smoking**

Smoking has long been identified as a strong risk factor for the development or progression of periodontitis and may limit the effectiveness of periodontal therapy.<sup>50-53</sup> The adjunctive use of a locally delivered, controlled-release antimicrobial may enhance the efficacy of SRP in smokers. In a 3 month trial SRP plus adjunctive DOX gel resulted in significantly greater probing depth reduction and clinical attachment gain versus SRP alone approximately equally in both smokers and non-smokers.<sup>54</sup> This result was consistent with subset analyses of current smokers, former smokers and non-smokers from 2 multi-center trials (DOX gel)<sup>55</sup> and smokers versus non-smokers (MIN microspheres).<sup>4</sup> These findings were replicated and extended by a later clinical trial (MIN microspheres).<sup>56</sup> Additional periodontal microbiological alterations suggested as beneficial changes in adjunctively treated sites compared with SRP alone have also been reported (DOX gel and MIN microspheres).<sup>56-58</sup> A 2 year trial with a small number of patients provided further supportive evidence of clinical efficacy (DOX gel).<sup>59</sup> Thus, adjunctive therapy may lessen the adverse impact of smoking on the periodontium and improve treatment outcomes in patients who smoke. A recent systematic review regarding DOX gel and MIN microspheres has suggested that the available evidence for an additional clinical benefit of adjunctive therapy is insufficient to support any definitive conclusions regarding smokers, noting that new randomized clinical trials are necessary to assess outcomes.<sup>60</sup>

### **Magnitude of Mean Probing Depth Reduction**

The 1996 World Workshop reported that the

mean probing depth reduction to be expected following SRP in sites with initial probing depth of 4 to 6 mm is 1.29 mm.<sup>61</sup> However, the data from randomized, multi-centered, blinded (mostly double-blinded) clinical trials that have been performed largely for FDA registration have consistently shown a mean reduction of about 1 mm in sites that were either 4 to 6 mm or 5 mm or greater (largely 5 to 6 mm) at baseline.<sup>2-4,20-22,37,62,63</sup> Whether the SRP procedures were performed within a pre-specified time limit or performed to the clinical endpoint of smooth roots with no time limit did not impact the extent of the result. The observed mean probing depth reduction has consistently been about 1 mm in at least 11 randomized trials, even when SRP procedures were performed with no time limitation.<sup>2-4,20-22,37,62,63</sup> In reported trials there was a variety of SRP methods used, along with a range of the number of included teeth with probing depth greater than 4 or 5 mm (generally 2 to 4 teeth).<sup>2-4,20-22,37,62,63</sup> One cannot assess the number of teeth that actually required SRP or the amount of time actually necessary to complete the instrumentation. Thus, comparisons of these reported trials with other reports in the literature are not appropriate, and the concerns do not detract from the findings of statistically significant changes within these internally controlled trials. Indeed, the largest numerical difference between treated and control arms was observed in a trial in which no time limitation for SRP procedures was noted, although this trial was conducted in a private practice setting.<sup>20</sup>

### **Trial Design**

The randomized clinical trials that confirmed the efficacy of locally delivered, controlled-release antimicrobials and supported FDA registration were well designed to give unequivocal outcomes. Concerns may always be raised regarding trial designs, but multi-centered clinical trials are enormously expensive and are difficult to perform. Trials must be designed appropriately to address the hypotheses of interest. The efficacy of locally delivered, controlled-release antimicrobials for the indication of periodontal disease to reduce probing depth or improve attachment level has been established in multiple trials, otherwise treated groups would not have separated from control (or would not have been equivalent to control).<sup>1-4,20-22</sup> These results have included trial designs both of adjunctive use with SRP or of monotherapy (Table II).

It has been speculated that trial results might have been different had control groups also received repeated treatment (i.e., repeated SRP).<sup>19</sup>

However, if the control group had received repeated SRP, the adjunctively treated group also would have had to receive repeated instrumentation to maintain design balance. Results for both groups may have been different, not just control. Additionally, locally delivered, controlled-release antimicrobials may be effective in the presence of calculus or with reduced amounts of instrumentation.<sup>64,65</sup> Additional instrumentation also would have made data interpretation more difficult; multiple treatments at multiple times make it more difficult to separate treatment effects meaningfully. Further, in support of the lack of an impact of additional instrumentation on the outcome, a similarly significant difference was reported when both treatment arms received SRP at baseline and a supragingival prophylaxis at 3 months.<sup>21</sup>

In summary, in the registration trials of local adjunctive therapy for 2 products (MIN microspheres, CHX chip),<sup>2,4</sup> all sites received SRP at baseline  $\pm$  adjunctive drug as per the randomization. At 3 and 6 months, sites randomized to drug received additional drug only if probing depth remained  $\geq 5$  mm (i.e., only a fraction of those sites). If the adjunctive therapy had no effect, probing depth at these sites would have trended back toward baseline as in the SRP alone sites; the observation that probing depth remained reduced clearly demonstrated that the drug was efficacious. The FDA agreed that the designs were adequate and well-controlled. An alternative design might have been to have all sites treated with mechanical instrumentation at 3 and 6 months with drug added per the randomization in sites with probing depth  $\geq 5$  mm. With this design, in order to have demonstrated significant changes, most likely a much greater number of patients would have had to have been studied for a greater length of time, a design that may not have practically been feasible.

Clinical trials need to be conducted in a reasonable time frame and with a reasonable number of subjects. Current designs are generally limited to the evaluation of surrogate endpoints (e.g., probing depth) rather than direct endpoints, such as tooth survival. Surrogate variables, however, are considered reasonable endpoints in periodontal clinical trials and relevant to tooth retention, although the inherent weaknesses of surrogate outcome variables have been noted.<sup>38,66,67</sup>

### **Clinical Use and Costs**

It has been noted that locally delivered, controlled-release antimicrobials are associated with greater acquisition costs in comparison with read-

ily available antiseptics such as povidone (PVP)-iodine or sodium hypochlorite.<sup>68</sup> These agents are discussed in more depth later in this paper. However, since these agents have not been adequately tested in clinical trials, and neither their safety nor their effectiveness have been established, these antiseptics must be considered investigational for the treatment of periodontitis and therefore not appropriate for inclusion in cost-effectiveness analyses.

In a clinical trial of more than 450 patients to study costs associated with the CHX chip, adjunctive therapy increased total treatment costs by approximately 50%, but reduced the likelihood for surgical treatment during the length of the trial by about 50% in comparison with patients treated conventionally.<sup>69</sup> Other dental treatment was sufficiently reduced to offset about half of the acquisition costs of the adjunctive antimicrobial. This result was consistent with a previously published modeled assessment regarding the CHX chip.<sup>70</sup> After 12 months, the examining periodontists recommended similar further amounts of surgery for both groups.<sup>69</sup> No information was available, however, regarding any further disease progression or tooth mortality or whether patients received any further surgical care. Additionally, no information was available for these patients regarding any differential outcomes with either follow-up surgical care or continued non-surgical maintenance with SRP and adjunctive therapy. Heasman et al have recently reviewed the cost-effectiveness of adjunctive antimicrobials in the treatment of periodontitis, and noted the continued need for long-term studies to assess effects on tooth mortality or other patient-reported outcomes.<sup>71</sup>

It has been suggested that the adjunctive benefits of locally delivered, controlled-release antimicrobials may only be short-term (i.e., clinical trials extended for only 6 or 9 months, however, these products can routinely be re-administered as needed.<sup>2,4,9,20-22</sup> A number of clinical trials, including studies of MIN microspheres, DOX gel and CHX chip, have provided evidence for the safety and efficacy of locally delivered, controlled-release antimicrobials for periodontal maintenance.<sup>17,72-80</sup> The same could be suggested regarding SRP, that the benefits of SRP may only be short-term. The clinical benefits of SRP seem to result from continued maintenance treatment for life. Similarly, the true benefits of locally delivered, controlled-release antimicrobials most likely will result from their routine use as adjuncts with SRP as well as in a periodontal maintenance program as indicated.

Finally, it has been suggested that other therapies (e.g., systemic antimicrobials) should be considered when there are multiple pockets.<sup>5,8,9</sup> It seems likely that locally delivered, controlled-release antimicrobials are effective because of the high concentration of active drug achieved and maintained in the gingival crevicular fluid (GCF),<sup>81-83</sup> perhaps especially needed because of the protective biofilm structure in the periodontal ecosystem<sup>84,85</sup> (for reviews, see Palmer<sup>86</sup> or Kuboniwa and Lamont<sup>87</sup>). Drug concentrations within the GCF with systemic antimicrobials are orders of magnitude less than those achievable with local agents and cannot provide an equivalent, alternative therapy.<sup>83,88</sup> Bacterial biofilms may be highly resistant to penetration by fluids,<sup>89</sup> providing further evidence for the critical need for high GCF concentrations of active antimicrobial, concentrations only achievable with suitable locally delivered controlled-release agents and not possible via systemic routes. Additionally, Drisko has suggested that the high concentrations of antimicrobial in the GCF as a result of local delivery may help to reach infected sites within the root or the pocket.<sup>90</sup> Other potential benefits include decreased systemic, off-target effects or a decreased risk for promoting microbial resistance.

### **Informed Consent and Legal Considerations**

Clinicians must treat all patients under the principles of informed consent, and all patients must provide their consent for all treatment. The FDA (adapted from 21CFR 50.25(a)<sup>91</sup>) describes 8 elements of informed consent that include:

1. A description of the planned treatment
2. A description of reasonably foreseeable risks or discomforts
3. A description of any reasonably expected benefits
4. Disclosure of appropriate alternative treatment
5. A description of procedures to maintain confidentiality
6. Disclosure of associated costs
7. Answering all questions
8. Disclosure that all treatment is voluntary

Appropriate treatment that satisfies the principles of informed consent includes treatment that is evidence-based, i.e., supported by appropriate research data. Since locally delivered, controlled-release antimicrobials as adjuncts have been consistently shown in clinical trials to enhance the efficacy of SRP within the timeframe of treatment, performing SRP, but not at least offering an ad-

junctive agent, seems to violate the principles of informed consent. Clinicians have a responsibility to offer all appropriate treatment options, including adjunctive therapy.

With respect to the issue of malpractice, undiagnosed or under-treated periodontitis are major sources of dental malpractice litigation.<sup>92</sup> Since SRP procedures are commonly considered the standard of care for non-surgical periodontal therapy, and available data support that adjunctive locally delivered, controlled-release antimicrobials enhance the efficacy of SRP, at least over the time frame of the clinical trials, then SRP plus adjunctive therapy could potentially be considered a new standard.<sup>7,9,32</sup> Other authors have noted the clinical relevance of locally delivered, controlled-release antimicrobials.<sup>15,17,39,43,44,73,90,93-109</sup> Would it be plausible to consider a possible defense in a malpractice litigation of alleged improperly managed periodontitis if it were claimed that the patient had not been offered maximally effective therapy (i.e., SRP with an adjunctive agent)?

### **Combination Adjunctive Therapy**

Locally delivered, controlled-release antimicrobials have been clearly shown to enhance the clinical efficacy of SRP. Adjunctive systemic therapy with low-dose (20 mg) doxycycline, given orally twice daily as a host-modulating agent (subsequently reported as a once daily, modified release formulation<sup>110</sup>), has also been shown to enhance the clinical efficacy of SRP.<sup>37,62,63</sup> For a review of matrix metalloproteinase modulation as a treatment strategy for periodontitis, see Reddy et al<sup>111</sup> or Ryan and Golub.<sup>112</sup> An obvious question is whether a combination of antimicrobial and host modulating adjunctive therapies will result in a greater clinical benefit compared with either adjunctive agent used alone.

In a 6 month clinical trial, combination adjunctive therapies resulted in significantly greater improvements in probing depth and clinical attachment as compared with SRP alone.<sup>113</sup> More sites showed a probing depth reduction  $\geq 2$  mm, and fewer sites had residual probing depth  $\geq 5$  mm.<sup>113</sup> Since the appropriate control groups (SRP plus single adjunctive therapy) were not included in the trial, definitive conclusions regarding any increased benefit from combination versus single adjunctive therapy cannot be made. The potential for combined adjunctive therapy to enhance clinical benefit is promising and warrants additional research.

## Locally Delivered Antimicrobials or Other Chemotherapeutics, not Controlled-Release

Many chemotherapeutic agents have been studied subgingivally as adjuncts to SRP as well, mainly via irrigation. None of these studies, however, satisfied the requirements necessary to make treatment recommendations (i.e., level 3 evidence based on adequate and well-controlled trials). A brief commentary regarding some of the most well published of these agents is in order, although a complete review of all tested adjunctive agents is out of scope for this paper.

**Povidone-iodine:** PVP-iodine is a broad spectrum antimicrobial reported to be effective against a broad range of periodontal pathogens and suggested as a beneficial adjunct to SRP as a subgingival irrigant.<sup>68,114-116</sup> Its use has recently been reviewed by Sahrman et al.<sup>117</sup> The authors concluded that the adjunctive use of PVP-iodine with SRP may result in an additional clinical benefit but also noted that most of the reviewed studies were small and of low quality, with discordant results - 7 studies were ultimately considered, of which 3 supported a benefit for adjunctive PVP-iodine, but the other four concluded that there was no evidence to support any additional adjunctive benefit.<sup>115,118-123</sup> The above studies and review considered a range of PVP-iodine administrations including, for example, irrigation, rinsing and single visit instrumentation. These were included in order to consider available data regarding PVP-iodine and periodontal treatment. Since the authors are not aware of any adequate and well-controlled trials comparing SRP plus adjunctive therapy with subgingivally irrigated PVP-iodine with SRP alone, no further comments can be made regarding the adjunctive efficacy of PVP-iodine.

**Chlorhexidine:** Chlorhexidine is a broad spectrum antimicrobial with a long history in dentistry, primarily as a supragingival mouth rinse.<sup>124</sup> The use of chlorhexidine as an adjunct to SRP administered via subgingival irrigation has been studied by many investigators. Although some trials suggest a clinical benefit,<sup>125-128</sup> the current consensus is that there is little evidence that subgingivally irrigated chlorhexidine, as an adjunct to SRP, offers any clinical benefit in comparison with SRP alone, that no additional probing depth reduction can be achieved with adjunctive irrigation.<sup>129-136</sup>

**Bleach/Peroxide:** Dilute bleach solutions or peroxides, alone or in combination, have been suggested to provide an additional clinical benefit as an adjunct to SRP. For example, activity

has been reported against periodontal pathogens in vitro and against *Actinobacillus* (now *Aggregatibacter*) *actinomycetemcomitans* clinically.<sup>137-139</sup> Sodium hypochlorite has also been suggested as an adjunct to curettage.<sup>140</sup> Other investigators, however, have reported no additional clinical benefit of salt and/or peroxide as an adjunct to SRP.<sup>136,141</sup> Minimal microbiological differences were noted as well.<sup>135,142</sup> Since appropriately designed randomized clinical trials have not been performed, there are insufficient data to support any conclusions regarding the use of these agents in periodontal therapy.

**Antibiotics and Other Agents:** Various antibiotics or other chemotherapeutics in non-controlled release formulations have been studied as subgingivally administered adjuncts to SRP. Topically delivered antimicrobial adjuncts may be useful for periodontitis, but definitive evidence is lacking.<sup>68,116,143-145</sup> For example, long term non-surgical periodontal therapy (15 months) that included SRP and subgingival minocycline ointment was reported as clinically and microbiologically superior to SRP alone.<sup>146</sup> Others have also reported additional clinical or microbiological benefit with adjunctive subgingival antibiotics (metronidazole or tetracycline),<sup>125,147</sup> but the absence of any further benefit has also been reported (tetracycline, minocycline).<sup>133,148,149</sup>

Substantial data from adequate and well-controlled, randomized clinical trials exist to support a clinical recommendation for the routine, adjunctive use of locally delivered, controlled-release antimicrobials in the treatment of periodontitis. With regard to locally delivered antimicrobials not in controlled-release formulations, there are some preliminary data that support the need for additional research of these agents for adjunctive clinical use. Until adequate and well-controlled clinical trials are conducted to establish safety and efficacy that could support regulatory registration, however, these agents should still be considered investigational in the U.S. as subgingivally administered adjuncts to SRP for the indication of periodontitis.

## Conclusion

There is strong evidence that locally delivered, controlled-release antimicrobials make SRP significantly more effective when used adjunctively, therefore, SRP without adjunctive treatment in appropriately eligible sites (i.e., probing depth  $\geq 5$  mm) may be less than maximally effective. As was stated at a symposium to consider the clinical significance of locally delivered antimicrobials at the

2001 AADR Meeting, “[t]he case is stronger for local delivery than for surgery.”<sup>15</sup>

It is no longer appropriate to determine therapy based solely on clinical judgment. The best an individual practitioner can do is to evaluate the evidence and suggest a treatment that the current data predict has the greatest probability for success. All available treatment options should be presented to the patient. Spielman and Wolff have commented on the unfortunate tendency for many dentists to base treatment on personal experience and not on reported evidence; they highlight that optimal care is evidence-based.<sup>150</sup> As an example of the sub-optimal care that can result from the lack of incorporation of the best available evidence into clinical practice, O’Donnell and colleagues recently reported on the underutilization of pit-and-fissure sealants in the dental office despite published ADA recommendations.<sup>151,152</sup>

There is strong evidence to support the routine, adjunctive use of locally delivered, controlled-release antimicrobials, and that these agents provide a significant additional clinical benefit. Many adjuncts are available for clinical use with SRP, including devices for subgingival cleaning and plaque removal and antiseptics or antibiotics for subgingival irrigation. The most robust data available, however, to support an adjunctive benefit to enhance the efficacy of SRP to reduce probing depth may be the data from clinical trials of locally delivered, controlled-release antimicrobials.

The appropriate clinical use of locally delivered, controlled-release antimicrobials therefore seems clear. SRP have previously been considered the non-surgical standard of care.<sup>7,9</sup> The evidence supports that adjunctive locally delivered, controlled-release antimicrobials make SRP more effective<sup>32</sup> with a known safety profile. In conclusion, based on the currently available data, when these agents are used routinely as adjuncts to SRP when indicated either as part of initial periodontal treatment or maintenance therapy, clinicians can expect an enhanced result as measured by a significantly greater mean reduction in probing depth as a result of treatment in comparison with SRP alone. Thus, SRP plus adjunctive therapy, used in a manner that is consistent with the approved label, could potentially be considered a new standard for non-surgical periodontal therapy.

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## Disclosure

Dr. Finkelman is a full time employee of AstraZeneca LP and owns stock in AstraZeneca. Dr. Polson reports no conflicts of interest.

## References

1. Goodson JM, Cugini MA, Kent RL, et al. Multi-center evaluation of tetracycline fiber therapy: II. clinical response. *J Periodont Res*. 1991;26(4):371-379.
2. Jeffcoat MK, Bray KS, Ciancio SG, et al. Adjunctive use of a subgingival controlled-release chlorhexidine chip reduces probing depth and improves attachment level compared with scaling and root planing alone. *J Periodontol*. 1998;69(9):989-997.
3. Garrett S, Johnson L, Drisko CH, et al. Two multi-center studies evaluating locally delivered doxycycline hyclate, placebo control, oral hygiene, and scaling and root planing in the treatment of periodontitis. *J Periodontol*. 1999;70(5):490-503.
4. Williams RC, Paquette DW, Offenbacher S, et al. Treatment of periodontitis by local administration of minocycline microspheres: a controlled trial. *J Periodontol*. 2001;72(11):1535-1544.
5. Greenstein G, Tonetti M. The role of controlled drug delivery for periodontitis. The Research, Science and Therapy Committee of the American Academy of Periodontology. *J Periodontol*. 2000;71(1):125-140.
6. Research, Science and Therapy Committee of the American Academy of Periodontology. Treatment of plaque-induced gingivitis, chronic periodontitis, and other clinical conditions. *J Periodontol*. 2001;72(12):1790-1800. Erratum in: *J Periodontol*. 2003 Oct;74(10):1568.
7. Bonito AJ, Lux L, Lohr KN. Impact of local adjuncts to scaling and root planing in periodontal disease therapy: a systematic review. *J Periodontol*. 2005;76(8):1227-1236. Erratum in: *J Periodontol*. 2006 Feb;77(2):326.
8. Greenstein G. Local drug delivery in the treatment of periodontal diseases: assessing the clinical significance of the results. *J Periodontol*. 2006;77(4):565-578.
9. American Academy of Periodontology statement on local delivery of sustained or controlled release antimicrobials as adjunctive therapy in the treatment of periodontitis. *J Periodontol*. 2006;77(8):1458.
10. Finkelman RD. Letter to the Editor. *J Periodontol*. 2000;71(12):1929-1932.
11. Soskolne WA. Letter to the Editor. *J Periodontol*. 2006;77(2):323.
12. Newman MG. Improved clinical decision making using the evidence-based approach. *Ann Periodontol*. 1996;1(1):i-ix.
13. Pihlstrom BL, Barnett ML. Design, operation, and interpretation of clinical trials. *J Dent Res*. 2010;89(8):759-772.
14. Hung JHM. Clinical Trial Designs. U.S. Food and Drug Administration. 2011.
15. Killoy WJ. The clinical significance of local chemotherapies. *J Clin Periodontol*. 2002;29(Suppl 2):22-29.
16. Kinane DF, Radvar M. A six-month comparison of three periodontal local antimicrobial therapies in persistent periodontal pockets. *J Periodontol*. 1999;70(1):1-7.
17. Rodrigues IF, Machion L, Casati MZ, et al. Clinical evaluation of the use of locally delivered chlorhexidine in periodontal maintenance therapy. *J Periodontol*. 2007;78(4):624-628.
18. Tomasi C, Koutouzis T, Wennström JL. Locally delivered doxycycline as an adjunct to mechanical debridement at retreatment of periodontal pockets. *J Periodontol*. 2008;79(3):431-439.
19. Research, Science and Therapy Committee [of the American Academy of Periodontology]. Letter to the Editor. *J Periodontol*. 2000;71(12):1932-1933.
20. Newman MG, Kornman KS, Doherty FM. A 6-month multi-center evaluation of adjunctive tetracycline fiber therapy used in conjunction with scaling and root planing in maintenance patients: clinical results. *J Periodontol*. 1994;65(7):685-691.
21. Paolantonio M, D'Angelo M, Grassi RF, et al. Clinical and microbiologic effects of subgingival controlled-release delivery of chlorhexidine chip in the treatment of periodontitis: a multicenter study. *J Periodontol*. 2008;79(2):271-282.
22. Soskolne WA, Heasman PA, Stabholz A, et al. Sustained local delivery of chlorhexidine in the treatment of periodontitis: a multi-center study. *J Periodontol*. 1997;68(1):32-38.

23. Pihlstrom B. Issues in the evaluation of clinical trials of periodontitis: a clinical perspective. *J Periodont Res.* 1992;27(Spec Iss):433-441.
24. Paquette DW. Pocket depth reduction as an outcome measure of inflammation and soft tissue changes in periodontitis trials. *J Int Acad Periodontol.* 2005;7(4 Suppl):147-156.
25. Khan S, Cabanilla LL. Periodontal probing depth measurement: A review. *Compend Contin Educ Dent.* 2009;30(1):12-14,16,18-21.
26. Renvert S, Persson GR. A systematic review on the use of residual probing depth, bleeding on probing and furcation status following initial periodontal therapy to predict further attachment and tooth loss. *J Clin Periodontol.* 2002;29(Suppl 3):82-89.
27. Page RC, DeRouen TA. Design issues specific to studies of periodontitis. *J Periodont Res.* 1992;27(4 Pt 2):395-404.
28. Acceptance Program Guidelines. Chemotherapeutic agents to slow or arrest periodontitis. Council on Scientific Affairs. American Dental Association. *J Periodontol.* 1998;69(9):1076-1080.
29. DeRouen TA, Hujoel PP, Mancl LA. Statistical issues in periodontal research. *J Dent Res.* 1995;74(11):1731-1737.
30. Reddy MS. Radiographic alveolar bone change as an outcome measure for therapies that inhibit bone loss or foster bone gain. *J Int Acad Periodontol.* 2005;7(4 Suppl):175-188.
31. Ryan ME. Clinical attachment level change as an outcome measure for therapies that slow the progression of periodontal disease. *J Int Acad Periodontol.* 2005;7(4 Suppl):162-171.
32. Hanes PJ, Purvis JP. Local anti-infective therapy: pharmacological agents. A systematic review. *Ann Periodontol.* 2003;8(1):79-98.
33. Newman MG, Caton JG, Gunsolley JC. The use of the evidence-based approach in a periodontal therapy contemporary science workshop. *Ann Periodontol.* 2003;8(1):1-11.
34. Goodson JM, Tanner ACR, Haffajee AD, Sornberger GC, Socransky SS. Patterns of progression and regression of advanced destructive periodontal disease. *J Clin Periodontol.* 1982;9(6):472-481.
35. Haffajee AD, Socransky SS, Goodson JM. Periodontal disease activity. *J Periodont Res.* 1982;17(5):521-522.
36. Socransky SS, Haffajee AD, Goodson JM, Lindhe J. New concepts of destructive periodontal disease. *J Clin Periodontol.* 1984;11(1):21-32.
37. Preshaw PM, Hefti AF, Novak MJ, et al. Subantimicrobial dose doxycycline enhances the efficacy of scaling and root planing in chronic periodontitis: a multicenter trial. *J Periodontol.* 2004;75(8):1068-1076.
38. Hujoel PP. Endpoints in periodontal trials: the need for an evidence-based research approach. *Periodontol 2000.* 2004;36:196-204.
39. Killoy WJ. The use of locally-delivered chlorhexidine in the treatment of periodontitis. Clinical results. *J Clin Periodontol.* 1998;25(11 Pt 2):953-958..
40. Palkanis KG. Surgical pocket therapy. *Ann Periodontol.* 1996;1(1):589-617.
41. Heitz-Mayfield LJA, Trombelli L, Heitz F, Needleman I, Moles D. A systematic review of the effect of surgical debridement vs. non-surgical debridement for the treatment of chronic periodontitis. *J Clin Periodontol.* 2002;29(Suppl 3):92-102.
42. Consensus report. Surgical pocket therapy. *Ann Periodontol.* 1996;1(1):618-620.
43. Killoy WJ. Chemical treatment of periodontitis: local delivery of antimicrobials. *Int Dent J.* 1998;48(3 Suppl 1):305-315.
44. Killoy WJ, Polson AM. Controlled local delivery of antimicrobials in the treatment of periodontitis. *Dent Clin North Amer.* 1998;42(2):263-283.
45. Reddy MS, Jeffcoat MK, Geurs NC, et al. Efficacy of controlled-release subgingival chlorhexidine to enhance periodontal regeneration. *J Periodontol.* 2003;74(4):411-419.
46. Minabe M, Kodama T, Kogou T, et al. Clinical significance of antibiotic therapy in guided tissue regeneration with a resorbable membrane. *Periodontol Clin Investig.* 2001;23(1):20-30.
47. Yoshinari N, Tohya T, Kawase H, et al. Effect of repeated local minocycline administration on periodontal healing following guided tissue regeneration. *J Periodontol.* 2001;72(3):284-295.



48. Aichelmann-Reidy ME, Reynolds MA. Predictability of clinical outcomes following regenerative therapy in intrabony defects. *J Periodontol.* 2008;79(3):387-393.
49. Jeffcoat MK, Palcanis KG, Weatherford TW, Reese M, Geurs NC, Flashner M. Use of a biodegradable chlorhexidine chip in the treatment of adult periodontitis: clinical and radiographic findings. *J Periodontol.* 2000;71(2):256-262.
50. Bergstrom J. Cigarette smoking as risk factor in chronic periodontal disease. *Community Dent Oral Epidemiol.* 1989;17(5):245-247.
51. Jansson LE, Hagstrom KE. Relationship between compliance and periodontal treatment outcome in smokers. *J Periodontol.* 2002;73(6):602-607.
52. Kaldahl WB, Johnson GK, Patil KD, Kalkwarf KL. Levels of cigarette consumption and response to periodontal therapy. *J Periodontol.* 1996;67(7):675-681.
53. Preber H, Linder L, Bergstrom J. Periodontal healing and periopathogenic microflora in smokers and non-smokers. *J Clin Periodontol.* 1995;22(12):946-952.
54. Tomasi C, Wennström JL. Locally delivered doxycycline improves the healing following non-surgical periodontal therapy in smokers. *J Clin Periodontol.* 2004;31(8):589-595.
55. Ryder MI, Pons B, Adams D, et al. Effects of smoking on local delivery of controlled-release doxycycline as compared to scaling and root planing. *J Clin Periodontol.* 1999;26(10):683-691.
56. Grossi SG, Goodson JM, Gunsolley JC, et al. Mechanical therapy with adjunctive minocycline microspheres reduces red-complex bacteria in smokers. *J Periodontol.* 2007;78(9):1741-1750.
57. Machion L, Andia DC, Saito D, et al. Microbiological changes with the use of locally delivered doxycycline in the periodontal treatment of smokers. *J Periodontol.* 2004;75(12):1600-1604.
58. M Shaddox L, Andia DC, Casati MZ, et al. Microbiologic changes following administration of locally delivered doxycycline in smokers: a 15-month follow-up. *J Periodontol.* 2007;78(11):2143-2149.
59. Machion L, Andia DC, Lecio G, et al. Locally delivered doxycycline as an adjunctive therapy to scaling and root planing in the treatment of smokers: a 2-year follow-up. *J Periodontol.* 2006;77(4):606-613.
60. Angaji M, Gelsky S, Nogueira-Filho G, Brothwell D. A systematic review of clinical efficacy of adjunctive antibiotics in the treatment of smokers with periodontitis. *J Periodontol.* 2010;81(11):1518-1528.
61. Cobb CM. Non-surgical pocket therapy: mechanical. *Ann Periodontol.* 1996;1(1):443-490.
62. Ciancio S, Ashley R. Safety and efficacy of sub-antimicrobial-dose doxycycline therapy in patients with adult periodontitis. *Adv Dent Res.* 1998;12(2):27-31.
63. Caton JG, Ciancio SG, Blieden TM, et al. Treatment with subantimicrobial dose doxycycline improves the efficacy of scaling and root planing in patients with adult periodontitis. *J Periodontol.* 2000;71(4):521-532.
64. Johnson LR, Stoller NH, Polson A, Harrold CQ, Ryder M, Garrett S. The effects of subgingival calculus on the clinical outcomes of locally-delivered controlled-release doxycycline compared to scaling and root planing. *J Clin Periodontol.* 2002;29(2):87-91.
65. Wennström JL, Newman HN, MacNeill SR, et al. Utilisation of locally delivered doxycycline in non-surgical treatment of chronic periodontitis. A comparative multi-centre trial of 2 treatment approaches. *J Clin Periodontol.* 2001;28(2):753-761.
66. Greenstein G. The use of surrogate variables to reflect long-term tooth survivability. *J Periodontol.* 2005;76(8):1398-1402.
67. Hujoel PP, Löe H, Anerud A, Boysen H, Leroux BG. The informativeness of attachment loss on tooth mortality. *J Periodontol.* 1999;70(1):44-48.
68. Jorgensen MG, Aalam A, Slots J. Periodontal antimicrobials--finding the right solutions. *Int Dent J.* 2005;55(1):3-12.
69. Henke CJ, Villa KF, Aichelmann-Reidy ME, et al. An economic evaluation of a chlorhexidine chip for treating chronic periodontitis: the CHIP (Chlorhexidine In Periodontitis) study. *J Am Dent Assoc.* 2001;132(11):1557-1569. Erratum in: *J Am Dent Assoc.* 2001 Dec;132(12):1658.

70. De Lissovoy G, Rentz AM, Dukes EM, et al. The cost-effectiveness of a new chlorhexidine delivery system in the treatment of adult periodontitis. *J Am Dent Assoc.* 1999;130(6):855-862.
71. Heasman PA, Vernazza CR, Gaunt FL, Pennington MWL. Cost-effectiveness of adjunctive antimicrobials in the treatment of periodontitis. *Periodontol 2000.* 2011;55(1):217-230.
72. Cortelli JR, Querido SMR, Aquino DR, Ricardo LH, Pallos D. Longitudinal clinical evaluation of adjunct minocycline in the treatment of chronic periodontitis. *J Periodontol.* 2006;77(2):161-166.
73. Dean JW, Branch-Mays GL, Hart TC, et al. Topically applied minocycline microspheres: why it works. *Compend Contin Educ Dent.* 2003;24(4):247-250, 252-257.
74. Heasman PA, Heasman L, Stacey F, McCracken GI. Local delivery of chlorhexidine gluconate (PerioChip) in periodontal maintenance patients. *J Clin Periodontol.* 2001;28(1):90-95.
75. Martorelli de Lima AF, Cury CC, Palioto DB, Duro AM, da Silva RC, Wolff LF. Therapy with adjunctive doxycycline local delivery in patients with type 1 diabetes mellitus and periodontitis. *J Clin Periodontol.* 2004;31(8):648-653.
76. Meinberg TA, Barnes CM, Dunning DG, Reinhardt RA. Comparison of conventional periodontal maintenance versus scaling and root planing with subgingival minocycline. *J Periodontol.* 2002;73(2):167-172.
77. Salvi GE, Mombelli A, Mayfield L, et al. Local antimicrobial therapy after initial periodontal treatment. *J Clin Periodontol.* 2002;29(6):540-550.
78. Soskolne WA, Proskin HM, Stabholz A. Probing depth changes following 2 years of periodontal maintenance therapy including adjunctive controlled release of chlorhexidine. *J Periodontol.* 2003;74(4):420-427.
79. Stabholz A, Shapira L, Mahler D, et al. Using the PerioChip in treating adult periodontitis: an interim report. *Compend Contin Educ Dent.* 2000;21(4):325-328, 330, 332.
80. Stabholz A, Soskolne WA, Friedman M, Sela MN. The use of sustained release delivery of chlorhexidine for the maintenance of periodontal pockets: 2-year clinical trial. *J Periodontol.* 1991;62(7):429-433.
81. Kim TS, Klimpel H, Fiehn W, Eickholz P. Comparison of the pharmacokinetic profiles of two locally administered doxycycline gels in crevicular fluid and saliva. *J Clin Periodontol.* 2004;31(4):286-292. Erratum in: *J Clin Periodontol.* 2004 May;31(5):412.
82. Soskolne WA, Chajek T, Flashner M, et al. An in vivo study of the chlorhexidine release profile of the PerioChip in the gingival crevicular fluid, plasma and urine. *J Clin Periodontol.* 1998;25(12):1017-1021.
83. Stoller NH, Johnson LR, Trapnell S, Harrold CQ, Garrett S. The pharmacokinetic profile of a biodegradable controlled-release delivery system containing doxycycline compared to systemically delivered doxycycline in gingival crevicular fluid, saliva, and serum. *J Periodontol.* 1998;69(10):1085-1091. Erratum in: *J Periodontol.* 1999;70(2):238.
84. Costerton W, Veeh R, Shirtliff M, Pasmore M, Post C, Ehrlich G. The application of biofilm science to the study and control of chronic bacterial infections. *J Clin Invest.* 2003;112(10):1466-1477. Erratum in: *J Clin Invest.* 2007;117(1):278.
85. Soukos NS, Mulholland SE, Socransky SS, Doukas AG. Photodestruction of human dental plaque bacteria: enhancement of the photodynamic effect by photomechanical waves in an oral biofilm model. *Lasers Surg Med.* 2003;33(3):161-168.
86. Palmer RJ Jr. Supragingival and subgingival plaque: paradigm of biofilms. *Compend Contin Educ Dent.* 2010;31(2):104-106, 108, 110
87. Kuboniwa M, Lamont RJ. Subgingival biofilm formation. *Periodontol 2000.* 2010;52(1):38-52.
88. Sakellari D, Goodson JM, Kolokotronis A, Konstantinidis A. Concentration of 3 tetracyclines in plasma, gingival crevice fluid and saliva. *J Clin Periodontol.* 2000;27(1):53-60.
89. Epstein AK, Pokroy B, Seminara A, Aizenberg J. Bacterial biofilm shows persistent resistance to liquid wetting and gas penetration. *Proc Natl Acad Sci U S A.* 2011;108(3):995-1000.
90. Drisko CH. The use of locally-delivered doxycycline in the treatment of periodontitis. Clinical results. *J Clin Periodontol.* 1998;25(11 Pt 2):947-952.
91. U.S. Food and Drug Administration. A Guide to Informed Consent - Information Sheet. U.S. Department of Health & Human Services. 2011.

92. Zinman E. Dental and legal considerations in periodontal therapy. *Periodontol 2000*. 2001;25:114-130.
93. Paquette DW. Locally administered antimicrobials for the management of periodontal infections. *Dent Today*. 2009;28(2):97-98, 100-101.
94. Krayner JW, Leite RS, Kirkwood KL. Non-surgical chemotherapeutic treatment strategies for the management of periodontal disease. *Dent Clin North Am*. 2010;54(1):13-33.
95. Hussein I, Ranka M, Gilbert A, Davey K. Locally delivered antimicrobials in the management of periodontitis: a critical review of the evidence for their use in practice. *Dent Update*. 2007;34(8):494-506.
96. Ryan ME. Nonsurgical approaches for the treatment of periodontal diseases. *Dent Clin North Am*. 2005;49(3):611-636.
97. Ciancio SG. Site specific delivery of antimicrobial agents for periodontal disease. *Gen Dent*. 1999;47(2):172-178, 181.
98. Johnson LR, Stoller NH. Rationale for the use of Atridox therapy for managing periodontal patients. *Compend Contin Educ Dent*. 1999;20(4 Suppl):19-25.
99. Killoy WJ. Assessing the effectiveness of locally delivered chlorhexidine in the treatment of periodontitis. *J Am Dent Assoc*. 1999;130(4):567-570.
100. Killoy WJ. Local delivery of antimicrobials: a new era in the treatment of adult periodontitis. *Compend Contin Educ Dent*. 1999;20(4 Suppl):13-18.
101. Magnusson I. Local delivery of antimicrobial agents for the treatment of periodontitis. *Compend Contin Educ Dent*. 1998;19:953-956, 958, 960.
102. Page RC. The microbiological case for adjunctive therapy for periodontitis. *J Int Acad Periodontol*. 2004;6(4 Suppl):143-149.
103. Paquette DW. Minocycline microspheres: a complementary medical-mechanical model for the treatment of chronic periodontitis. *Compend Contin Educ Dent*. 2002;23(5 Suppl):15-21.
104. Paquette DW, Hanlon A, Lessem J, Williams RC. Clinical relevance of adjunctive minocycline microspheres in patients with chronic periodontitis: secondary analysis of a phase 3 trial. *J Periodontol*. 2004;75(4):531-536.
105. Pavia M, Nobile CGA, Angelillo IF. Meta-analysis of local tetracycline in treating chronic periodontitis. *J Periodontol*. 2003;74(6):916-932.
106. Soskolne WA. Subgingival delivery of therapeutic agents in the treatment of periodontal diseases. *Crit Rev Oral Biol Med*. 1997;8(2):164-174.
107. Tonetti MS. Local delivery of tetracycline: from concept to clinical application. *J Clin Periodontol*. 1998;25(11 Pt 2):969-977.
108. Van Dyke TE. The clinical significance of new therapies for the management of periodontal disease. *J Int Acad Periodontol*. 2005;7(4 Suppl):191-196.
109. Van Dyke TE, Offenbacher S, Braswell L, Lessem J. Enhancing the value of scaling and root-planing: Arestin clinical trial results. *J Int Acad Periodontol*. 2002;4(3):72-76.
110. Preshaw PM, Novak MJ, Mellonig J, et al. Modified-release subantimicrobial dose doxycycline enhances scaling and root planing in subjects with periodontal disease. *J Periodontol*. 2008;79(3):440-452.
111. Reddy MS, Geurs NC, Gunsolley JC. Periodontal host modulation with antiproteinase, anti-inflammatory, and bone-sparing agents. A systematic review. *Ann Periodontol*. 2003;8(1):12-37.
112. Ryan ME, Golub LM. Modulation of matrix metalloproteinase activities in periodontitis as a treatment strategy. *Periodontol 2000*. 2000;24:226-238.
113. Novak MJ, Dawson DR 3rd, Magnusson I, et al. Combining host modulation and topical antimicrobial therapy in the management of moderate to severe periodontitis: a randomized multicenter trial. *J Periodontol*. 2008;79(1):33-41.
114. Nakagawa T, Hosaka Y, Ishihara K, et al. The efficacy of povidone-iodine products against periodontopathic bacteria. *Dermatology*. 2006;212(suppl 1):109-111.
115. Hoang T, Jorgensen MG, Keim RG, Pattison AM, Slots J. Povidone-iodine as a periodontal pocket disinfectant. *J Periodont Res*. 2003;38(3):311-317.
116. Slots J. Selection of antimicrobial agents in periodontal therapy. *J Periodont Res*. 2002;37(5):389-398.

117. Sahrman P, Puhan MA, Attin T, Schmidlin PR. Systematic review on the effect of rinsing with povidone-iodine during nonsurgical periodontal therapy. *J Periodont Res*. 2010;45(2):153-164.
118. Forabosco A, Spinato S, Grandi T, Prini M. A comparative study between different techniques in non-surgical periodontal treatment. *Minerva Stomatol*. 2006;55(5):289-296.
119. Rosling B, Hellström MK, Ramberg P, Socransky SS, Lindhe J. The use of PVP-iodine as an adjunct to non-surgical treatment of chronic periodontitis. *J Clin Periodontol*. 2001;28(11):1023-1031.
120. Del Peloso Ribeiro E, Bittencourt S, Ambrosano GM, et al. Povidone-iodine used as an adjunct to non-surgical treatment of furcation involvements. *J Periodontol*. 2006;77(2):211-217.
121. Koshy G, Kawashima Y, Kiji M, et al. Effects of single-visit full-mouth ultrasonic debridement versus quadrant-wise ultrasonic debridement. *J Clin Periodontol*. 2005;32(7):734-743.
122. Leonhardt A, Bergström C, Krok L, Cardaropoli G. Healing following ultrasonic debridement and PVP-iodine in individuals with severe chronic periodontal disease: a randomized controlled clinical study. *Acta Odontol Scand*. 2006;64(5):262-266.
123. Zanatta GM, Bittencourt S, Nociti FH Jr, Sallum EA, Sallum AW, Casati MZ. Periodontal debridement with povidone-iodine in periodontal treatment: short-term clinical and biochemical observations. *J Periodontol*. 2006;77(3):498-505.
124. Löe H, Schiott CR. The effect of mouthrinses and topical application of chlorhexidine on the development of dental plaque and gingivitis in man. *J Periodont Res*. 1970;5(2):79-83.
125. Khoo JGL, Newman HN. Subgingival plaque control by a simplified oral hygiene regime plus local chlorhexidine or metronidazole. *J Periodont Res*. 1983;18(6):607-619.
126. Reynolds MA, Lavigne CK, Minah GE, Suzuki JB. Clinical effects of simultaneous ultrasonic scaling and subgingival irrigation with chlorhexidine. Mediating influence of periodontal probing depth. *J Clin Periodontol*. 1992;19(8):595-600.
127. Southard SR, Drisko CL, Killoy WJ, Cobb CM, Tira DE. The effect of 2% chlorhexidine digluconate irrigation on clinical parameters and the level of *Bacteroides gingivalis* in periodontal pockets. *J Periodontol*. 1989;60(6):302-309.
128. Vignarajah S, Newman HN, Bulman J. Pulsated jet subgingival irrigation with 0.1% chlorhexidine, simplified oral hygiene and chronic periodontitis. *J Clin Periodontol*. 1989;16(6):365-370.
129. Chapple ILC, Walmsley AD, Saxby MS, Moscrop H. Effect of subgingival irrigation with chlorhexidine during ultrasonic scaling. *J Periodontol*. 1992;63(10):812-816.
130. Cosyn J, Sabzevar MM. A systematic review on the effects of subgingival chlorhexidine gel administration in the treatment of chronic periodontitis. *J Periodontol*. 2005;76(11):1805-1813.
131. Guarnelli ME, Franceschetti G, Manfrini R, Trombelli L. Adjunctive effect of chlorhexidine in ultrasonic instrumentation of aggressive periodontitis patients: a pilot study. *J Clin Periodontol*. 2008;35(4):333-341.
132. Krust KS, Drisko CL, Gross K, Overman P, Tira DE. The effects of subgingival irrigation with chlorhexidine and stannous fluoride. A preliminary investigation. *J Dent Hyg*. 1991;65(6):289-295.
133. MacAlpine R, Magnusson I, Kiger R, Crigger M, Garrett S, Egelberg J. Antimicrobial irrigation of deep pockets to supplement oral hygiene instruction and root debridement. I. Bi-weekly irrigation. *J Clin Periodontol*. 1985;12(7):568-577.
134. Quirynen M, Mongardini C, De Soete M, et al. The rôle of chlorhexidine in the one-stage full-mouth disinfection treatment of patients with advanced adult periodontitis. Long-term clinical and microbiological observations. *J Clin Periodontol*. 2000;27(8):578-589.
135. Wennström JL, Dahlén G, Gröndahl K, Heijl . Periodic subgingival antimicrobial irrigation of periodontal pockets II. Microbiological and radiographical observations. *J Clin Periodontol*. 1987;14(10):573-580.
136. Wennström JL, Heijl L, Dahlén G, Gröndahl K. Periodic subgingival antimicrobial irrigation of periodontal pockets (I). Clinical observations. *J Clin Periodontol*. 1987;14(9):541-550.
137. Miyasaki KT, Genco RJ, Wilson ME. Antimicrobial properties of hydrogen peroxide and sodium bicarbonate individually and in combination against selected oral, gram-negative, facultative bacteria. *J Dent Res*. 1986;65(9):1142-1148.

138. Miyasaki KT, Wilson ME, Genco RJ. Killing of *Actinobacillus actinomycetemcomitans* by the human neutrophil myeloperoxidase-hydrogen peroxide-chloride system. *Infect Immun*. 1986;53(1):161-165.
139. Wikesjö UME, Reynolds HS, Christersson LA, Zambon JJ, Genco RJ. Effects of subgingival irrigation on *A. actinomycetemcomitans*. *J Clin Periodontol*. 1989;16(2):116-119.
140. Kalkwarf KL, Tussing GJ, Davis MJ. Histologic evaluation of gingival curettage facilitated by sodium hypochlorite solution. *J Periodontol*. 1982;53(2):63-70.
141. Pihlstrom BL, Wolff LF, Bakdash MB, et al. Salt and peroxide compared with conventional oral hygiene. I. Clinical results. *J Periodontol*. 1987;58(5):291-300.
142. Wolff LF, Pihlstrom BL, Bakdash MB, et al. Salt and peroxide compared with conventional oral hygiene. II. Microbial results. *J Periodontol*. 1987;58(5):301-307.
143. Flemmig TF, Petersilka G, Völp A, et al. Efficacy and safety of adjunctive local moxifloxacin delivery in the treatment of periodontitis. *J Periodontol*. 2011;82(1):96-105.
144. Jorgensen MG, Slots J. The ins and outs of periodontal antimicrobial therapy. *J Calif Dent Assoc*. 2002;30(4):297-305.
145. Rosling BG, Slots J, Christersson LA, Gröndahl HG, Genco RJ. Topical antimicrobial therapy and diagnosis of subgingival bacteria in the management of inflammatory periodontal disease. *J Clin Periodontol*. 1986;13(10):975-981.
146. van Steenberghe D, Rosling B, Söder PO, et al. A 15-month evaluation of the effects of repeated subgingival minocycline in chronic adult periodontitis. *J Periodontol*. 1999;70(6):657-667.
147. Stabholz A, Nicholas AA, Zimmerman GJ, Wikesjö UME. Clinical and antimicrobial effects of a single episode of subgingival irrigation with tetracycline HCl or chlorhexidine in deep periodontal pockets. *J Clin Periodontol*. 1998;25(10):794-800.
148. Timmerman MF, van der Weijden GA, van Steenberghe TJM, Mantel MS, de Graaff J, van der Velden U. Evaluation of the long-term efficacy and safety of locally-applied minocycline in adult periodontitis patients. *J Clin Periodontol*. 1996;23(8):707-716.
149. Silverstein L, Bissada N, Manouchehr-Pour M, Greenwell H. Clinical and microbiological effects of local tetracycline irrigation on periodontitis. *J Periodontol*. 1988;59(5):301-305.
150. Spielman AI, Wolff MS. Overcoming barriers to implementing evidence-based dentistry. Letter to the editor. *J Dent Educ*. 2008;72(3):263-264.
151. O'Donnell JA, Modesto A, Oakley M, Polk DE, Vallapil B, Spallek H. Sealants and dental caries. Insights into dentists' behaviors regarding implementation of clinical practice recommendations. *J Am Dent Assoc*. 2013;144(4):e24-e30.
152. Beauchamp J, Caufield PW, Crall JJ, et al. Evidence-based clinical recommendations for the use of pit-and-fissure sealants: a report of the American Dental Association Council on Scientific Affairs. *J Am Dent Assoc*. 2008;139(3):257-268.

# Short Report

## Strategies for Service-Learning Assessment in Dental Hygiene Education

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### Introduction

#### Service-Learning

Service-learning pedagogy has its roots in the Cooperative Education Movement of the early 1900s.<sup>1</sup> Service-learning is a teaching and learning strategy that is also known as experiential learning.<sup>2</sup> Service-learning is a structured instructional activity that incorporates purposeful community service, definitive preparation and guided reflection. Due to the community focus, the term service-learning is often used interchangeably with the term “community engaged teaching and learning.”<sup>3</sup> Regardless of whether it is referred to as experiential learning, community engaged learning or service-learning, this instructional approach seeks to enhance scholarship experiences through hands-on participation while edifying civic responsibility and fortifying communities.<sup>2</sup> An important component of service-learning is its reciprocal nature; it is the intent of experiential learning programs that both student and community benefit. Table I shows the definition of service-learning promoted by the Community-Campus Partnerships for Health (CCPH) whose goal is to promote health equity and social justice through partnerships between communities and academic institutions.<sup>4</sup> Unique to service-learning in health professions is the concept of influencing health disparities and the quality of life of communities.<sup>5</sup> CCPH has an enormous amount of resources for the health professional educator. Dental hygiene educators can access suggestions regarding service-learning projects, partnerships, research and assessment strategies via CCPH’s easy to navigate website. Service-learning in health professions education occurs largely within higher education institutions.

#### Service-Learning in Higher Education

The history of service-learning in higher education is well documented. In 1969, educational leaders

### Abstract

**Purpose:** A large body of literature exists on the instructional pedagogy known as service-learning. Service-learning is a teaching and learning approach characterized by the dental hygiene student’s practical application of academic studies and occurs within a community setting, to the benefit of both the student and community. Dental hygiene educators use service-learning to enhance student knowledge and application of oral health curriculum. This manuscript reports on the importance of service-learning assessment to the National Dental Hygiene Research Agenda as well as the future of the profession of dental hygiene and the successful strategies in service-learning evaluation available for utilization by dental hygiene educators.

**Keywords:** service-learning, dental hygiene education, assessment strategies

This study supports the NDHRA priority area, **Professional Education and Development:** Investigate curriculum models for training and certification of competencies in specialty areas.

gathered in Atlanta to discuss service-learning and the importance of employing the instructional strategy throughout American colleges and universities. They produced 3 recommendations for institutions of higher education in regards to service-learning:<sup>6</sup>

1. Colleges and universities should encourage students to participate in community service, help to make sure that academic learning is part of this service and to give academic recognition for that learning
2. Colleges and universities, private organizations, and federal, regional and state governments should provide the opportunities and funds for students wanting to participate in service-learning
3. Students, public and private agency officials, and college and university faculty should all participate in the planning and running of service-learning programs

Since these initial recommendations, scholars and educational policymakers alike have met regularly to discuss and determine best practice ideas for service-learning instruction. Currently, service-learning is part of a larger movement within higher education described as community engagement.

Community engagement is a systematic, structured, integrative continuum of teaching, research and service in institutions of higher learning.<sup>5</sup>

There is a broad spectrum of service-learning programming in health professions education. While scholarship suggests that the projects, institutionalization, goals and impact of service-learning in health professions education vary, there are common characteristics that represent authentic service-learning experiences which can be identified. Service-learning in health professions education is often noted within the literature as positive, meaningful, cooperative, addressing complex health issues, engaging in contextual problem-solving, promoting critical thinking skills, deep learning, and supportive of emotional, social and cognitive learning and development in students.<sup>2</sup>

### **Service-Learning in Dental Hygiene Education**

In 2006, Dr. Karen Yoder developed a framework for service-learning in dental and dental hygiene education (Figure 1). Yoder outlined 10 components that characterize true service-learning and described how educators can develop more effective service-learning curriculum, including the use of appropriate assessment strategies.<sup>7</sup> Yoder noted that "Integrating service-learning into the dental curriculum will create a deeper understanding of the dynamics, the assets, and the challenges of the community and its relationship to oral and general health."<sup>7</sup> Based on the foundational concepts within service-learning theory, dental hygiene education programs have developed service-learning projects similar to others within health professions education.<sup>8,9</sup> Yoder's components of scholarship, partnerships, professional growth and sustainable programs can be identified within the articles dedicated to recounting service-learning experiences within dental hygiene education. Dental hygiene students have engaged in service-learning experiences in rural communities, urban areas within the U.S. and even internationally.<sup>10</sup> Research supports Yoder's findings that students gain a greater understanding of access to care issues while working with underserved communities.<sup>11</sup> Research also notes that dental hygiene students who engage in service-learning experiences acquire enhanced clinical and interpersonal skills working with diverse populations and a deeper appreciation of the complexity of oral health disparities.<sup>12</sup> Assessment of service-learning experiences within the dental hygiene curriculum is an important component to understanding student outcomes as it relates to service-learning pedagogy. Goals for service-learning experiences can be as broad and varying as the projects themselves. Desired student

Table I: Definition of Service-Learning

- Service-learning strives to achieve a balance between service and learning objectives - in service-learning partners must negotiate the differences in their needs and expectations
- Service-learning places an emphasis on addressing community concerns and broad determinants of health
- In service-learning, there is the integral involvement of community partners - service-learning involves a principle-centered partnership between communities and health professions schools
- Service-learning emphasizes reciprocal learning - In service-learning, traditional definitions of "faculty," "teacher" and "learner" are intentionally blurred. We all learn from each other
- Service-learning emphasizes reflective practice - In service-learning, reflection facilitates the connection between practice and theory and fosters critical thinking
- Service-learning places an emphasis on developing citizenship skills and achieving social change - many factors influence health and quality of life. The provision of health services is not often the most important factor. In service-learning, students place their roles as health professionals and citizens in a larger societal context

outcomes may include cultural competency, richer understanding of access to care issues, civic learning, greater clinical competence and interpersonal growth.<sup>13</sup>

### **Appropriate Assessment Strategies Move Dental Hygiene Education Forward**

The National Dental Hygiene Research Agenda (NDHRA) encourages research that supports educational methods that "prepare dental hygienists to meet the increasingly complex oral health needs of the public" and emphasizes the importance of validating reliable methods to "evaluate student critical thinking and decision-making skills."<sup>14</sup> For dental hygiene educators, the NDHRA outlines the essential contribution of high-quality evidenced-based curriculum, the use of well established assessment strategies and appropriate research methods aimed at growing the dental hygiene profession toward greater autonomy. While the NDHRA guides dental hygiene educators, the recently released American Dental Hygienists' Association (ADHA) Environmental Scan Dental Hygiene at the Crossroads of Change pushes them to see beyond the current status of dental hygiene education.<sup>15</sup> Emerging opportunities for dental hygienists in a variety of practice settings as well as the development of an expanded scope of practice summarized by the ADHA Envi-

ronmental Scan, challenges dental hygiene educators to extend more opportunities for students to go beyond the walls of the classroom and develop superior critical thinking skills. There is a clear need for dental hygiene programs to implement proven educational strategies that allow students to experience greater independence and diversity in patient populations and work environment all the while preparing them as the next generation of dental hygiene leaders. Service-learning provides this opportunity to dental hygiene students and continues to meet the guidelines for educational programs in the current instruction and curriculum accreditation standards set by the Commission on Dental Accreditation (CODA).<sup>16</sup>

### Strategies for Service-Learning Assessment

A broad variety of assessment strategies for service-learning instruction exist. There are a number of resources dental hygiene educators can access to assist in the development of appropriate assessment tools for their individual service-learning instruction. These resources include online guidebooks. For example, the CPH offers a workbook entitled "Methods and Strategies for Assessing Service-Learning in Health Professions."<sup>17</sup> The National Service-Learning Clearinghouse has a toolkit dedicated to service-learning in higher education.<sup>18</sup> Merely accessing service-learning related research articles from professional journals and magazines can spark new and innovative ideas for dental hygiene faculty.

### Reflection Exercises

Traditional service-learning assessment is based on simple reflection exercises. Service-learning integrates numerous exigent reflection activities that are continuous, initiate deep thinking and engender scrutiny from students about themselves and concerning the experience.<sup>19</sup> Research indicates that structured reflection activities help students apply learning to real-life situations. This in turn allows them to develop stronger problem-solving skills. Finally, research verifies participating in reflection activities is associated with improved openness to new ideas, the capacity to see issues in a new way and the aptitude to examine situations methodically.<sup>20</sup> Guided reflection activities include critical thinking questions addressed by students during the service-learning experience, end of the course questionnaires and continuous journaling assignments. Journaling throughout a service-learning experience can assist students to view their experience holistically so that at its end they can see the progress they made and evaluate the success of the project in terms of meeting the needs of the com-

Figure 1: Framework for Service-Learning in Dental and Dental Hygiene Education



munity.<sup>21</sup> Technology and the use of social media have impacted reflective exercises, allowing for almost immediate assessment of the service-learning experience. The ease and familiarity of mobile computing via laptops and smart phones allow dental hygiene students to tweet, blog, share videos and utilize internet discussion boards to review their service-learning activity and connect with faculty and fellow students. Dental hygiene educators have found success in utilizing online directed journaling as a reflection and sharing strategy.<sup>22</sup> It is important to note that with journaling, and especially online blogging or other social media outlets, a high level of care needs to be practiced to protect confidentiality, safety and privacy of all individuals involved in the service-learning activity.

### Advocacy Assignments

Less traditional, yet remarkably valuable assessment strategies of activities service-learning include advocacy assignments. Related to increasing understanding of civic responsibilities and the public health role of the dental hygienist, students participate in social justice activities as well as legal and political issues within marginalized communities during service-learning instruction. Course requirements could include engaged critical analysis items, such as formal communication assignments related to advocacy. For example, students may participate in setting agendas for advocacy meetings, attending and critiquing legislative sessions, developing scripts for making phone calls or sending emails, or



even write formal, professional letters to newspapers, government organizations, legislators or lobbyists.<sup>23</sup>

### **Interdisciplinary Approaches**

With the boundaries of health careers ever evolving, the development of a dental hygiene student's ability to collaborate, communicate effectively and work well with other health care practitioners is essential to the future of the dental hygiene profession.<sup>24</sup> One assessment strategy aimed toward evaluating these characteristics in students during interdisciplinary service-learning instruction is small group problem solving.<sup>25</sup> Students from various disciplines are grouped, participate in the service-learning activity, identify and develop a plan to address one problem for the community they served. This activity may include addressing a specific access to care dilemma for a particular population within a community. This might also be an opportunity to focus on cultural competency. This interprofessional group process is monitored by faculty and a formal presentation of group solutions is made to the entire assembly of interdisciplinary students and faculty. Evaluation of both the team process and the solution presentation allows faculty to determine the student's professionalism, collaboration, leadership and communication skills.

### **Focus Groups**

Similarly, the use of focus groups to assess service-learning activities in dental hygiene curriculum can have a two-fold purpose. First, the dental hygiene student focus groups can appraise student perceptions of the service-learning experience. Student perceptions are often difficult to measure; surveys are frequently skewed, whereas observations during focus groups can give healthy insight into student non-verbal behaviors, in depth discussion of thought processes and more truthful opinions.<sup>26</sup> Second, the dental hygiene student focus group can assist in service-learning instruction evaluation and development, thus contributing to important qualitative research within the field of service-learning pedagogy. Certainly focus group assessment might assist the student in identifying the benefits, both clinical and academic, of their service-learning experiences.

### **Self-Assessment Measures**

Finally, self-assessment measures are the most common strategy utilized in the evaluation of service-learning instruction. Self-assessment measures can include surveys, questionnaires, guided critical thinking exercises, and written assignments geared toward developing a student's ability to critique their own beliefs, attitudes and behavior, communicate opinions, and express them professionally.<sup>27</sup> Self-assessment measures are helpful strategies in dental hygiene education, allowing them to meet CODA standards for an educational programs capacity for teaching ethics and professionalism.<sup>16</sup> And according to the ADHA Environmental Scan, to be a registered dental hygienist in the future, students will need leadership skills including self-awareness, flexibility and a greater capability to communicate professionally with other practitioners. Self-assessments as a strategy for evaluating service-learning instruction helps develop these skills for the dental hygiene student.

### **Conclusion**

Service-Learning pedagogy is being successfully utilized in higher education and health professions education in a variety of ways. Service-learning in dental hygiene education has incorporated many of the 10 components outlined by Yoder.<sup>7</sup> A comprehensive approach to service-learning program development, curriculum design and assessment is imperative to the success of service-learning instruction within the field of dental hygiene education.<sup>15</sup> There is an opportunity to strengthen dental hygiene curriculum via the use of suitable assessment strategies for service-learning activities. Dental hygiene educators have a broad selection of service-learning assessment strategies to choose from including reflection exercises, advocacy assignments, interdisciplinary approaches, focus groups and self-assessment measures. Influenced by current accreditation standards and the predicted massive shifts in the professional environment, appropriate assessment strategies for dental hygiene service-learning instruction can contribute to the successful development of the next generation of highly skilled, collaborative and competent dental hygiene practitioners.

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## References

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1. What is service-learning? National Service-Learning Clearinghouse [Internet]. [cited 2012 May 24]. Available from: <http://www.service-learning.org/what-service-learning>
2. Learn and Serve America. What is service-learning? [Internet]. 2004. Power Point presentation at the 2004 National Conference on Community Volunteering and National Service in Kansas City, KS.
3. Reynolds P. Community engagement: what's the difference between service-learning, community service, and community-based research? *J Phys Ther Educ.* 2009;23(2):3-9.
4. Seifer SD. Service-Learning: Community-campus partnerships for health professions education. *Acad Med.* 1998;73(3);273-277.
5. Transforming communities & higher education. Community-Campus Partnerships for Health [Internet]. 2010 [cited 2012 May 24]. Available from: <http://depts.washington.edu/ccph/servicelearningres.html>
6. History of service-learning in higher education. National Service-Learning Clearinghouse [Internet]. 2008 [cited 2012 Sept 4]. Available from: [http://www.servicelearning.org/what\\_is\\_service-learning/history/index.php](http://www.servicelearning.org/what_is_service-learning/history/index.php)
7. Yoder KM. A framework for service-learning in dental education. *J Dent Educ.* 2006;70(2):115-123.
8. Kruger B.J, Roush C, Olinzock BJ, et al. Engaging nursing students in a long term relationship with a home-base community. *J Nurs Educ.* 2010;49(1):10-16.
9. Lukes SM, Miller FY. Faith-based initiatives and service-learning: a match made in heaven. *J Dent Hyg.* 2006;80(1):13.
10. Tabor RG, Carter DM, Kovar M, et al. International service learning. *J Dent Hyg.* 2008;82(5):49.
11. Aston-Brown RE, Branson B, Gadbury-Amyot, CC, et al. Utilizing public health clinics for service-learning rotations in dental hygiene: a four year retrospective study. *J Dent Educ.* 2009;73(3):358.
12. Coulton K. Assessment of a service-learning component at the Armstrong Atlantic State University Dental Hygiene Department. *J Dent Hyg.* 2008;82(5):65.
13. Lautar CJ, Miller FY. Service-Learning and Dental Hygiene: a literature review. *J Dent Hyg.* 2007;81(3):64.
14. National dental hygiene research agenda. American Dental Hygienists' Association [Internet]. 2007 [cited 2012 May 24]. Available from: [www.adha.org/downloads/Research\\_agenda%20-ADHA\\_Final\\_Report.pdf](http://www.adha.org/downloads/Research_agenda%20-ADHA_Final_Report.pdf)
15. Dental hygiene at the crossroads of change: Environmental scan 2011. American Dental Hygienists' Association [Internet]. 2011 [cited 2012 May 24]. Available from: [www.adha.org/downloads/ADHA\\_Environmental\\_Scan.pdf](http://www.adha.org/downloads/ADHA_Environmental_Scan.pdf)
16. Accreditation standards for dental hygiene education programs. Commission on Dental Accreditation [Internet]. 2012 [cited 2012 May 24]. Available from: <http://www.ada.org/sections/educationAndCareers/pdfs/dh.pdf>
17. Methods and strategies for assessing service-learning in health professions. Community-Campus Partnerships for Health [Internet]. 2001 [cited 2012 Sept 4]. Available from: <http://www.ccph.info/>
18. Faculty toolkit for service-learning in higher education. National Service-Learning Clearinghouse [Internet]. 2007 [cited 2012 Sept 4]. Available from: <http://www.servicelearning.org/toolkits>
19. Standards and indicators for effective service-learning practice. RMC Research Corporation [Internet]. 2012 [cited 2012 May 24]. Available from: [http://www.servicelearning.org/instant\\_info/fact\\_sheets/k-12\\_facts/standards](http://www.servicelearning.org/instant_info/fact_sheets/k-12_facts/standards)
20. Eyler J, Giles DE Jr. Where's the Learning in Service-Learning. San Francisco, CA: Jossey-Bass; 1999.
21. Ivey J. Service-learning research. *Ped Nurs.* 2011;37(2):74,83.
22. Gwozdek AE, Klausner CP, Kerschbaum WE. Online directed journaling in clinical dental hygiene education. *J Dent Hyg.* 2009;83(1):12.

23. Jovanovic S. Communication as critical inquiry in service-learning. *Acad Exchange Quart.* 2003;7(2):81-85.
24. Connors K, Seifer S, Sebastian J, Cora-Bramble D, Hart R. Interdisciplinary collaboration in service-learning: Lessons from the health professions. *Mich J Comm Service-Learning.* 1996;3(1):113-127.
25. Yelsma P. Combining small group problem solving with service-learning. *Mich J Comm Service-Learning.* 1994;1(1):62-69.
26. Schmiede A. Using focus groups in service-learning: Implications for practice and research. *Mich J Comm Service-Learning.* 1995;2(1):63-71.
27. Kearney K. Students' self-assessment of learning through service-learning. *Am J Pharm Educ.* 2004;68(1):1-5.

# Short Report

## Access to Oral Health Care in the Georgia Prison System

Kandyce J. Mack, RDH, MS; Marie Collins, RDH, EdD

### Introduction

The Eighth Amendment of the U.S. Constitution establishes the basis for inmates' rights to health care by prohibiting cruel and unusual punishment. The 1976 U.S. Supreme Court case, *Estelle v. Gamble*, 429 U.S. 97, further clarifies that inmates must be protected from "deliberate indifference to their serious medical needs."<sup>1</sup> The National Commission on Correctional Health Care (NCCHC) was established in the early 1970s to ensure the health care rights of inmates. This organization publishes its Standards for Health Services as a guide to health care delivery for correctional institutions and serves as a health care accrediting body for these facilities. Legally, inmates can expect to receive routine and emergency medical, dental and psychiatric health services.<sup>1</sup>

The Georgia Department of Corrections is the legal authority that oversees the state's prison facilities, which is described as the fifth largest prison system in the country, housing more than 60,000 inmates.<sup>2</sup> The Office of Health Services of the Georgia Department of Corrections is responsible for the provision of health care to inmates housed in the Georgia prison system. Minimum standards of health care identified by the Office of Health Services include "the right to access to care, the right to care that is ordered, and the right to a professional medical judgment."<sup>3</sup> According to Georgia's Correctional Standards of Health Care, inmates should receive a dental examination within 30 days of incarceration, oral hygiene instruction, and care by a dentist when medically necessary.<sup>1</sup> The purpose of this article is to provide an overview of the access to oral health care of inmates in the Georgia prison system. Potential barriers to dental and dental hygiene services are identified and suggestions are offered to improve access to care for inmates.

Dental care is listed as an essential health service by the National Commission on Correctional Health

### Abstract

**Purpose:** The Eighth Amendment of the U.S. Constitution establishes the basis for inmates' rights to health care and includes both routine and emergency medical, dental and psychiatric treatment. According to Georgia's Correctional Standards of Health Care, inmates should receive a dental examination within 30 days of incarceration, instructions in oral hygiene and other care by a dentist when medically necessary. The July, August and September 2011 Georgia Department of Corrections' profiles of active inmates in the Georgia prison system reveal a need for both dental and dental hygiene services. The purpose of this article is to provide an overview of the access to oral health care of inmates in the Georgia prison system. Potential barriers to dental and dental hygiene services are identified and suggestions are offered to improve access to care for inmates.

**Keywords:** standard of care, prisoners, health services accessibility, oral health

This study supports the NDHRA priority area, **Health Services**

**Research:** Assess the impact of increasing access to dental hygiene services on the oral health outcomes of underserved populations.

Care. As required by Georgia's Correctional Standards of Health Care, prisoners are examined to assess their dental health needs. The July, August and September 2011 reports from the Georgia Department of Corrections identify the dental health status of active inmates in the prison system upon intake into the facility (Table I).<sup>4-6</sup>

According to The Standard Operating Procedures, Department of Corrections, the dental examination performed at intake is done by a dentist and consists of dental history, teeth charting, and a hard and soft tissue evaluation. For each level of need, the subjective "D" or Dental Code index 1, 2, 3, 4 or 5 is assigned by a licensed dentist at the time of inmate intake. During the months of August 2011, September 2011 and October 2011, 49 to 50% of inmates presented with minimal routine dental health needs (D1), about 35% presented with moderate cavities and/or gum disease (D2) and 14 to 15% presented with extensive gum disease and/or widespread decay (D3). Less than 0.05% of inmates presented with an urgent need for dental services (D4), and even less presented with life-threatening disease,

Table I: Recent Dental Status of Active Georgia Inmates

Date	Inmates Assessed (n)	D1 Minimal routine dental health needs	D2 Moderate cavities and/or gum disease	D3 Extensive gum disease and/or widespread decay	D4 Urgent need for dental services	D5 Life-threatening disease or extreme pain or infection
August 3, 2011	46,658	23,056 49.41%	16,501 35.37%	7084 15.18%	16 0.03%	1 0.01%
September 21, 2011	47,400	23,904 50.43%	16,718 35.27%	6760 14.26%	17 0.04%	1 0.01%
October 5, 2011	47,371	23,977 50.62%	16,725 35.31%	6652 14.04%	16 0.03%	1 0.01%

extreme pain or infection (D5). Dental treatment in the Georgia Department of Corrections requires a fee for service and/or copay.

The Standard Operating Procedures state that inmates with dental conditions that require immediate attention (D4 and D5) will be scheduled for treatment. However, non-emergency dental treatment (D1, D2 and D3) must be requested by the inmate. Emergency treatment in the Georgia Department of Corrections consists of extractions while non-emergency treatment consists of routine prophylaxis, scaling and root planning, closed flap curettage, amalgams, composites, temporary restorations, and removable prosthodontics.

In 1995, Thorburn proposed that one reason for the extensive dental needs of prisoners is that dentists are hired to perform both dental and dental hygiene services and often work without the aid of a dental assistant.<sup>7</sup> In 2004, the Georgia Department of Corrections' 30 prison dental clinics employed full-time 8 dental hygienists and 22 dentists.<sup>8</sup>

The author communicated personally with the Dental Director for Georgia Department of Corrections, Dr. Cynthia S. Ditslear: Currently in Georgia, each of the 38 state prisons employs 1 dentist. This ratio of approximately one dentist to 1,600 inmates is well over the suggested 1:1,200 standard of care. Of the 38 state prisons, 29 employ 9 dental hygienists. There are 9 prisons which do not employ dental hygienists - the dentist is responsible for preventive and restorative services (Ditslear CS, personal communication, June 27, 2012). Dental expenditures steadily reduced from \$3,871,600 in 2003 to \$3,424,995 in 2004 to \$1,475,072 in 2006.<sup>8,9</sup> This reduction is reportedly due to a decrease in funding for oral health care.<sup>8</sup>

In an unpublished inquiry to dental directors of state prisons, Dr. Cynthia S. Ditslear found that Georgia is behind 3 of its surrounding states in meeting the standard of care for dentist to inmate ratio. The ratio of dentists to inmates is 1:1,200 in South

Carolina, 1:1,026 in North Carolina and 1:1,200 to 1,250 in Florida.

In 2002, the president of the Medical College of Georgia appointed a group of various Georgia leaders in dentistry, education and government to the MCG Dental Task Force who later released a report that included 28 recommendations related to dental training programs, access to care and the shortage of dental faculty. In 2007, the president charged the dental school dean to revisit these recommendations and a new task force was formed called the Georgia Dental Task Force. A 2008 report from this effort recommended coordination between the state's only dental school and the Georgia Department of Corrections on Human Resources and Service Administration (HRSA) grants.<sup>10</sup>

The Task Force projected a graduating dental class of 100 students by the year 2016 and further recommended the use of Department of Corrections and Department of Juvenile Justice facilities as educational training sites for dental students.<sup>10</sup> There are currently 16 accredited dental hygiene programs in Georgia. In 2011, these programs graduated approximately 215 students.<sup>11</sup> Surveys are needed to determine staffing needs for dental hygienists, dental assistants and dentists in Georgia Department of Corrections facilities and how best to publicize these needs to graduating and practicing dental professionals.

## Conclusion

The Georgia Correctional Standards of Care emphasizes that access to health care is guaranteed by the U.S. Constitution. Dental care is a component of this health care right. One of the goals of Healthy People 2020 is to improve the oral health of U.S. citizens by increasing access to dental care. Georgia Department of Corrections' 2011 statistics provide the dental status for inmates as they are admitted to the prison. However, there are no formal monitoring mechanisms to track the current oral health status of inmates. Non-emergency and preventive

dental treatment is not rendered unless inmates request and pay a fee for the services (C.S. Ditslear, personal communication, June 27, 2012).

With the disproportional increase of dental hygienists employed by the Georgia Department of Corrections compared to the number of prisons and increase in inmate population, training opportunities could be explored for dental hygiene as well as dental students. Current and proposed oral health care workforce models, such as the dental therapist, are excellent strategies to address dental needs for this growing and underserved population.<sup>12</sup> Longitudinal assessments of the oral health care status of inmates are needed to determine the extent of a workforce shortage for this population. Having this data would aid the Georgia Department

of Corrections in achieving its mission "to provide the required constitutional level of health care in the most efficient, cost effective and humane manner possible, while protecting the public health interests of the citizens of the State of Georgia."<sup>3</sup>

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## References

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1. Understanding Georgia's Correctional Standards of Health Care: What Policymakers and Stakeholders Need to Know. A Report to the Georgia Department of Corrections. Public Works, LLC [Internet]. 2003 [cited 2012 February 26]. Available from: <http://www.dcor.state.ga.us/pdf/ReportCorrectionalHealthCareSystem.pdf>
2. FY 2010 Annual Report. Georgia Department of Corrections [Internet]. 2010 [cited 2012 February 26]. Available from: [http://www.dcor.state.ga.us/Research/Annual/GDC\\_annual\\_report\\_FY2010.pdf](http://www.dcor.state.ga.us/Research/Annual/GDC_annual_report_FY2010.pdf)
3. Georgia Department of Corrections Health Services Mission Statement. The Required Constitutional Level of Health Care. Georgia Department of Corrections Office [Internet]. 2011 [cited 2012 February 26]. Available from: <http://www.dcor.state.ga.us/pdf/hsovrFY11.pdf>
4. Georgia Department of Corrections Operations, Planning, and Training Division. Inmate Statistical Profile 03-AUG-11. Georgia Department of Corrections [Internet]. 2011 [cited 2012 February 26]; 55. Available from: [http://gdc.ga.gov/Research/Monthly/Profile\\_all\\_inmates\\_2011\\_07.pdf](http://gdc.ga.gov/Research/Monthly/Profile_all_inmates_2011_07.pdf)
5. Georgia Department of Corrections Operations, Planning, and Training Division. Inmate Statistical Profile 21-SEP-11. Georgia Department of Corrections [Internet]. 2011 [cited 2012 February 26]; 51. Available from: [http://gdc.ga.gov/Research/Monthly/Profile\\_all\\_inmates\\_2011\\_08.pdf](http://gdc.ga.gov/Research/Monthly/Profile_all_inmates_2011_08.pdf)
6. Georgia Department of Corrections Operations, Planning, and Training Division. Inmate Statistical Profile 05-OCT-11. Georgia Department of Corrections [Internet]. 2011 [cited 2012 February 26]; 54. Available from: [http://gdc.ga.gov/Research/Monthly/Profile\\_all\\_inmates\\_2011\\_09.pdf](http://gdc.ga.gov/Research/Monthly/Profile_all_inmates_2011_09.pdf)
7. Thorburn KM. Health care in correctional facilities. *West J Med.* 1995;163(6):560-564.
8. Treadwell HM, Casares C, Norris K. Oral Health: Who Cares? Who Should Care? Community Voices [Internet]. 2007 [cited 2012 February 26]. Available from: [http://www.communityvoices.org/Uploads/LatestOralHealth\\_00108\\_00168.pdf](http://www.communityvoices.org/Uploads/LatestOralHealth_00108_00168.pdf)
9. Georgia Department of Corrections Office of Health Services. Georgia Department of Corrections Health Services Overview for FY 2003. Georgia Department of Corrections [Internet]. 2003 [cited 2012 February 26]. Available from: <http://www.dcor.state.ga.us/pdf/hsovrFY03.pdf>
10. Georgia Dental Task Force. Shining the Light on the State's Dental Education Needs. Georgia Health Sciences University [Internet]. 2008 [cited 2012 February 26]. Available from: <http://www.georgiahealth.edu/dentalmedicine/documents/FinalReport.pdf>
11. Number of Dental Hygiene Education Programs Offered by State. American Dental Hygienists' Association [Internet]. 2012 [cited 2012 July 4]. Available from: [http://www.adha.org/downloads/edu/Ed\\_Program\\_Map.pdf](http://www.adha.org/downloads/edu/Ed_Program_Map.pdf)
12. Oral Health Care Workforce – Current and Proposed Providers. American Dental Hygienists' Association [Internet]. 2010 [cited 2012 July 4]. Available from: [http://www.adha.org/governmental\\_affairs/downloads/Oral\\_Health\\_Care\\_Workforce\\_Chart.pdf](http://www.adha.org/governmental_affairs/downloads/Oral_Health_Care_Workforce_Chart.pdf)

## A Qualitative Case Study of the Legislative Process of the Hygienist-Therapist Bill in a Large Midwestern State

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### Introduction

The burden of dental disease in America is disproportionately distributed - 75% of dental disease in the U.S. is found in 25% of the population.<sup>1</sup> In addition, the number of Americans without dental insurance exceeds the number of those without medical insurance by 3 to 1.<sup>2</sup> Approximately 44% of adults in the U.S. have no dental insurance, and although children have been reported to take precedence through programs like Medicaid, pediatric dental coverage is not considerably better.<sup>3</sup> The economic impact of lack of access to dental care includes a reported loss of 164 million work hours and 51 million school hours in a single year in the U.S.<sup>4</sup>

The public's lack of access to oral health care services is impacting not only dentistry, but also the entire medical community. Less than 50% of dentists participate in public health insurance programs, and of those who do, many restrict the number of patients they are willing to serve.<sup>5,6</sup> Because of this, many patients who are unable to find a dentist flock instead to the emergency medical setting, where they are guaranteed treatment with insurance coverage or at no cost.<sup>7</sup> Pettinato et al found that providing emergency room (ER) care to children on Medicaid for dental related issues is 10-times more costly than the estimated cost of preventive oral health care.<sup>8</sup> Of particular interest to the current study is a study conducted by Davis et al evaluating dental-related emergency room visits in 5 metropolitan hospital systems in a Midwestern state over the period of 1 year.<sup>5</sup> The state studied by Davis is the same state in which this case study was conducted. Results showed that in the 5 hospital systems there was, in the span of 1 year, a total of 10,325 dental-

related ER visits resulting in a cost of \$4,743,519 (a median cost of \$525 per visit). Approximately 20% of patients seen for ER visits returned 2 to 11 times throughout the year for additional dental pain. A recently released study completed by PEW discusses the costs and inconvenience to both patients and providers of the use of ERs as a substitute for the treatment

### Abstract

**Purpose:** Inequitable access to dental care contributes to oral health disparities. Midlevel dental provider models are utilized across the globe as a way to bridge the gap between preventive and restorative dental professionals and increase access to dental care. The purpose of this study was threefold: to examine lessons learned from the state legislative process related to creation of the hygienist-therapist in a Midwestern state, to improve understanding of the relationship between alternative oral health delivery models and public policy and to inform the development and passage of future policies aimed at addressing the unmet dental needs of the public.

**Methods:** This research investigation utilized a qualitative research methodology to examine the process of legislation relating to an alternative oral health delivery model (hygienist-therapist) through the eyes of key stakeholders. Interview data was analyzed and then triangulated with 3 data sources: interviews with key stakeholders, documents and researcher participant field notes.

**Results:** Data analysis resulted in consensus on 3 emergent themes with accompanying categories. The themes that emerged included social justice, partnerships and coalitions, and the legislative process.

**Conclusion:** This qualitative case study suggests that the creation of a new oral health workforce model was a long and arduous process involving multiple stakeholders and negotiation between the parties involved. The creation of this new workforce model was recognized as a necessary step to increasing access to dental care at the state and national level. The research in this case study may serve to inform advocates of access to oral health care as other states pursue their own workforce models.

**Keywords:** health care disparities, delivery of health care, dental hygienists, health promotion, public policy

This study supports the NDHRA priority area, **Health Promotion/ Disease Prevention:** Identify, describe and explain mechanisms that promote access to oral health care, e.g., financial, physical, transportation.



of dental pain.<sup>9</sup> This research expressed that the average cost (nearly \$6,500) for dental problems treated in-hospital is nearly 10-times the cost of the preventive care that could be completed in a dentist's office to prevent it, and out of these emergency rooms visits 80% still need the subsequent care of a dentist.<sup>8,10</sup>

Repeated ER use for oral pain underscores a pressing need to develop increased access for preventive and non-emergent oral health care.<sup>7</sup> U.S. hospitals saw a 16% increase in dental related ER visits from 2006 to 2009, effecting an already burdened emergency room system.<sup>9,11</sup> According to the American College of Emergency Physicians:

"[Emergency rooms] are increasingly crowded, over capacity, and overwhelmed [leading to] increasing delays in care, even when [patients] are in pain or experiencing a heart attack."<sup>12</sup>

These statistics illustrate the high cost to the individual, the medical profession, the state and ultimately to society when access to oral health care services are not effectively addressed.

Ease of access to oral health care providers directly correlates with the frequency and quality of oral health care received by the public. Furthermore, it may be noted that fewer oral health care providers means less overall access to oral health care. Unfortunately, the past 2 decades have seen a decrease in the number of practicing dentists throughout the U.S.<sup>13</sup> Nationwide, 2 dentists will retire for every dental graduate replacing them over the next decade.<sup>14</sup> These workforce trends contribute to workforce shortage areas (particularly in rural communities). Additionally, a lack of insurance and/or low Medicaid reimbursement rates result in un-served or underserved populations, even in urban communities.

The more than 100 million Americans who lack dental insurance and are unable to pay for services provided in the predominantly private, fee-for-service dental practice setting call into question the effectiveness of our current oral health care delivery model in the U.S.<sup>15</sup> For adults and children who are able to obtain dental coverage under Medicaid, PEW found that only one-third to one-half of dentists are even treating Medicaid patients.<sup>16</sup> This is assumed to be due to the perceived high-cost and low-reimbursement rates when treating these patients. As a result, dental needs become more severe as less treatment is performed.

Alternative workforce models have been proposed as one means of addressing mal-distributions of health care providers. The medical community has utilized alternative workforce models as a way to extend the practice of physicians. Since the mid-1960s, the

use of nurse practitioners and physician's assistants has provided greater access for a greater number of people seeking medical care.<sup>9-11</sup> Not only have these professionals been utilized to increase access to primary care for many populations, they have also been instrumental in increasing health care awareness and disease prevention.

Research has begun to emerge in the U.S. exploring how other countries have turned to alternative workforce models by using allied dental professions as a strategy for increasing access to oral health care services. Some of the countries studied include New Zealand, Canada and the United Kingdom (U.K.), as well as the state of Alaska.<sup>17</sup> Nash describes the dental therapist/oral health therapist model as the "best practice" solution used in over 53 countries around the globe.<sup>18</sup> He goes on to explain that this new provider model is meant to "prevent oral disease in our children, and to care for it when preventive efforts fail." The therapy model suggested by Nash is based on utilizing an undergraduate-level therapy-only model that does not include the hygiene-based therapist model discussed in this case study.

Of all the practitioner models studied, the one most closely aligned to the hygienist-therapist model that has been proposed in specific states in the U.S. is the U.K.'s dental therapist. This model builds off the already existing workforce of dental hygienists by expanding the educational programming to include therapist services. The dental therapist has been in existence since 1916, but was expanded in the U.K. in 2002 to have the therapist education program combined with dental hygiene education programs.<sup>19-21</sup> In addition to the dental hygiene scope of practice, dental therapists also provide primary dental restorative services to public health and private practice patients throughout the nation. Dr. Pamela Ward, a U.K. dentist, mentions that with the materialization of the therapist, and its ability to treat the primary dental needs of the patient, "the highly developed skills in which dentists have been trained can be more effectively deployed... Consequently, the patient will be placed in the hands of the dental professional who is most appropriately qualified to carry out the job."<sup>22</sup>

Given the current research on alternative workforce models in other countries, and the current lack of access to oral health care services in the state in which this study was conducted, the logic behind the hygienist-therapist model in this Midwestern state was two-fold: tap into an existing workforce with a long history of demonstrated effectiveness and expand on their education, and expand their scope of practice (as a result of their advanced education) to provide much-needed oral health care services to citizens who otherwise lack access. Many states have already de-

veloped advanced and collaborative practice acts that allow dental hygienists decreased dentist supervision (or even independent practice), increased scope of practice to include limited therapeutic and restorative procedures, and treatment of patients outside the traditional dental setting.<sup>23-25</sup> Although many provider models may be necessary to adequately increase access to dental care, the hygienist-therapist model is aimed directly at elevating the skill of a current profession, thus allowing for an accredited educational curriculum that builds upon existing knowledge rather than starting with a new, entry-level provider. While 27 states have passed legislation to allow dental hygienists to perform some sort of restorative services, the lack of increased scope of practice within these models to provide restorative care that includes the removal of decay has been detrimental and is an ongoing problem. The lack of access to dentists, who hold the primary responsibility of removing decay, continues to be a significant barrier to access to comprehensive dental care and adequate oral health. Through the legislative efforts that have resulted in the hygienist-therapist in the state in which this case study was conducted, the U.S. dental care team is expanding as a significant number of states pursue this and the hygienist-therapist model in their practice act. These providers will be used to expand access to care; they will collaborate with dentists and refer patients needing services beyond their scope of practice (e.g., oral surgery, endodontic). A recent study's simulation of the impact of adding 1 "hygienist-therapist" model provider, called the Advanced Dental Therapist (ADT), to a solo general dentist practice showed a 28% increase in office profits in a setting serving 20% Medicaid patients (the profit margin increased 52% with practices seeing less than 20% Medicaid patients).<sup>26</sup>

Limited research exists on the newly developed hygienist-therapist in the U.S., despite interest in expanding the dental workforce to allow for increased access to dental care. The purpose of this study was to examine lessons learned from the state legislative process related to creation of the hygienist-therapist in a Midwestern state, to improve understanding of the relationship between alternative oral health delivery models and public policy, and to inform the development of future policies and procedures aimed at addressing the unmet dental needs of the public.

## Methods and Materials

A qualitative case study design was conducted in a large, Midwestern state from August 2007 to May 2009. This timeframe allowed the researchers to capture data in the early stages of legislation, including the identification of stakeholders involved in access to oral health care, up to the point of the final legislation that approved the addition of a new workforce model. Consistent with

case study design, 3 sources of data were used for the purpose of triangulation: interviews with key stakeholders, documents and researcher participant field notes.

Using a semi-structured interview protocol, 4 questions were developed for the interviews:

1. What was the process that lead up to the act of pursuing legislation regarding the dental therapist and advanced dental therapist?
2. What groups or stakeholders were most involved or influential in the process, what portions of the process were they most involved in and how did they work together?
3. What was the level of stakeholder influence on the workgroup that was assigned the role of scrutinizing the details of the bill and how did it fit in to the process?
4. How was the adoption process handled in the end? Who were the primary influential members and how were the final decisions negotiated between parties prior to being presented to the legislature for a vote?

Research started with 1 initial informant who was very involved in the legislative process. The primary researcher then utilized the snowball technique to interview 4 additional interviews of stakeholders in locations convenient for the participant. The snowballing technique helps identify cases from people familiar with the topic and who can identify other people who have information-rich knowledge on the same issue or topic.<sup>27</sup> A total of 5 transcribed interviews were completed that included 2 dentists, a dental educator, a lobbyist and a state legislative official. Using the constant comparative method outlined by Lincoln and Guba, the principle investigator and 2 faculty researchers separately analyzed and unitized the data by identifying key themes.<sup>27</sup> The next step involved the process of achieving consensus.

For the purposes of this study, the American Dental Hygienists' Association's (ADHA) Advanced Dental Hygiene Practitioner (ADHP) and the hygienist-therapist approved for the Midwestern state being studied will be defined as "advanced providers" due to their characteristics which mirror the medical model's advanced providers (in medicine, the advanced providers are educated at a graduate or doctoral level). It must also be recognized that the legislation passed in the Midwestern state in which this study occurred included 2 levels of providers that resulted in the initiation of 2 separate educational programs. One level of provider includes the hygienist-therapist model that mirrors the ADHP model culminating in a graduate level degree. The other model is based on a therapy-only model which does not include dental hygiene education and culminates in either an undergraduate or graduate level degree.

## Results

In qualitative research “words” comprise the data. Analysis of participant interviews resulted in consensus on three emergent themes with accompanying categories (Table I). The themes that emerged include: Social Justice, Partnerships and Coalitions, and Legislative Process. Table II is a schematic representation of the emergent themes, along with the data used for triangulation, member checking and creating an audit trail.<sup>27</sup> Validity of the emergent themes was achieved through the process of triangulation, including the use of case documents and researcher observations. All 3 themes were individually emphasized by all stakeholders interviewed. Categories were coded and assigned under the associated theme and utilized for triangulation purposes with the researcher-observer’s field notes and supportive data.

### Themes

*Social Justice:* Within the social justice theme the categories of advocacy, awareness, personal experiences, passion, workforce models and funding sources are brought to life through the stakeholder interviews, documents and the researcher’s observations. As one legislator proponent recalled:

“...I said in every committee...why it was that we were there. I would ...say, ‘thank you for coming. This is not about you.’ And then I would say to the dentists and dental students. ‘Thank you for coming. This is not about you.’ And on down the list. To the dental school dean, to our Higher Ed institutions... ‘...It’s about people like Deamonte Driver. It’s about people that aren’t here tonight... it’s an emotional issue, and if you can sort of keep everyone focused on why it is that we’re here I think that’s helpful...”

While oral health disparities are a national issue, this case study focused on disparities at the state level and proposed legislation for alternative dental workforce models to address issues surrounding the state’s access to oral health care. The theme of social justice is best described by Ozar and Sokol, who speak of social justice in terms of the social nature of dentistry plus the issue of justice.<sup>28</sup> They advocate that while dentistry involves one-to-one relationships, it is, by its very nature, a social enterprise that works within the context of social structures. These social structures determine how to distribute a society’s resources and govern their exchange. In terms of justice, Ozar and Sokol state, “... when a society’s structures for distributing resources are ethically sound, a common adjective used to describe such a society is just. When a society’s structures are ethically deficient, one proper term is unjust.”<sup>28</sup>

The connection between social justice and legislation was made by other proponents. As one dental educator

Table I: Emergent Themes from Data Analysis – Number of Total Responses by Theme

Emergent Theme	Number of Responses
Social Justice	44
<ul style="list-style-type: none"> <li>• Advocacy</li> <li>• Awareness</li> <li>• Personal Experiences</li> <li>• Passion</li> <li>• Workforce Models</li> <li>• Funding Sources</li> </ul>	
Partnerships & Coalitions	35
<ul style="list-style-type: none"> <li>• Stakeholders (risk takers and leaders)</li> <li>• Collaboration</li> <li>• Broaden the Field</li> <li>• Communication</li> </ul>	
Legislative Process	93
<ul style="list-style-type: none"> <li>• Formal</li> <li>• Compromise</li> <li>• Lobbying</li> <li>• Informal</li> <li>• Toll</li> <li>• Intimidation</li> <li>• Controversy</li> <li>• Semantics</li> <li>• Mentors</li> <li>• Rookies</li> </ul>	

Table II: Interview, Documents, Personal Experience Reviewed for the Study

Interviews	Documents
2 Dentist Proponents	Field Notes
1 Dental Educator Proponent	Legislative bills, amendments, committee meeting agendas & expert testimony from bill proponents and opponents
1 Proponent Lobbyist	Proponents Position Papers, Letters and Handouts, Opponents Position Papers
1 State Legislator Proponent	

proponent stated:

“In 2000 and in 2003 were...Surgeon General Satcher’s ‘Oral Health in America’ and then Surgeon General Carbone’s ‘National Call to Action’ [that] really put to the forefront the [oral health] disparities that certain...population groups have.”

And the same conclusion, from a lobbyist proponent:

“Lobbying groups identified from the start that the focus needed to be on access.”

Despite the different backgrounds of each of the stakeholders, each and every one noted the definite connection the legislation had to social justice as proponent groups rallied with one another to support the increase in access to dental care through expanding the dental workforce. Advocating for this type of legislation was emphasized as an important means for achieving social justice as it relates to access to oral health care.

It was recognized early on in the process that the level of awareness of oral health care access and disparity within the dental community itself, as well as the level of awareness within the overall public, was minimal, therefore, documents were created at varying levels of detail to best educate all individuals working or residing in the state. Educational materials used to advance advocacy and an awareness of the access-to-care issue were created, some independently and others jointly, by dental hygienists' associations at both the state and national level, by the state safety net coalition, and by the university developing the educational guidelines. These documents were used widely, from the state capitol, health care clinics and dental education institutions, to coffee house informational sessions and email campaigns. These educational documents and FAQs were developed prior to the timeframe in which this study took place, and were used for 2 years prior to legislative action as an avenue to increase awareness of the access to oral health care disparities existing in the state.

Throughout the 2 years of advocacy prior to legislative action, many personal experiences about lack of access to needed oral health care services were shared, not only by people within the profession, but also by the general public. As one dental educator proponent noted:

"...I have siblings and a father who need dental care... it became a personal cause as well as professional."

A university official shared his own experience as a young adult of finding it difficult to access necessary dental care and be seen by a dentist. It was clear during the advocacy and education process that the lack of oral health care access cut across all ages, races and socioeconomic statuses. As a result, many stakeholders came to the proponents' discussion table as passionate advocates before they even became actively involved in creating legislation.

While for some it was personal experience that got them involved, for others it was the sudden comprehension of the scope of the problem that existed in the state. One state legislator proponent commented on his/her new-found awareness:

"I came in to office in 2007...[legislator proponent mentor] directed me to go to this health policy conference...I had no passion at the time for oral health... I

went to a session on dental therapy... I wasn't thinking of my own district, but in [a specific state district] we have a large Native American population... and from that I guess I got my fire... she [legislative mentor] said, 'You go. You go and see what you can do.'"

As the legislative process started moving, the awareness of the overall proponent group translated into action, and its member organizations, in turn, became passionate advocates to educate those within their spheres of influence about the access crisis in the state. As one dental educator proponent put it:

"We didn't have the money, but we had the work power [doers] and the people and the passion...I really think it boils down to it was the right thing to do. Legislators were tired of hearing about it. It was all about access. It wasn't about the hygiene association, or the proponent university or the safety net. It was about the patient."

Documents, newspaper articles and listening sessions educated individuals and groups on how access to oral health care was a significant barrier for many state residents. Naturally, following education, the question was: How should the state address this issue? The solution proposed within the proponent groups associated with the safety net coalition was to consider a new dental workforce model. Through talking with various groups, it became clear that this provider level needed to be able to provide preventive services in combination with restorative services in order create a permanent fix in the system of care. As an example of the barriers that exist in access to dental care, a dental hygienist working as a Collaborative Practice Dental Hygienist (CPDH) through a dentist described patients she was treating in a rural school district. She related how many of her elementary-aged patients would come back 2, 6 or even 18 months after an initial evaluation revealing incipient decay because they had had no success in finding transportation to the referred dentist after the initial visit (and therefore delayed treatment), their decay had often worsened significantly. One 8-year-old child's decay had deteriorated into 4 significantly compromised permanent first molars that were clearly decayed and infected. These teeth appeared to be in need of endodontic treatment, or even extraction. Although the CPDH was able to go to the location where the patient was and create some limited access to care, she still could not give her patient increased access to a dentist - the only one able to diagnose and treat the decay. Safety Net members and proponent groups identified a parallel concept that had been developed by the ADHA which addressed these issues and agreed that this would be the avenue through which the proponent group would pursue a hygienist-therapist workforce model. Many avenues were researched, but in the end a state university received a proposal for a dental hygiene-based master's level provider. The new

provider would take on the mid-level provider model that had been utilized in the medical field for the nurse practitioner and physician assistant since the 1960s.<sup>29</sup>

Past efforts to increase access to care had brought funding questions to light as the legislative process began and the cost of the new endeavors had started to unfold. One of the dental educator proponents interviewed for this study was involved in starting within their educational facility a public program community clinic with a sliding fee scale. The clinic was made possible through a state grant that allowed for the opening of the clinic; it was met with an overwhelming response that resulted in a wait list or the need to find other avenues of care in additional facilities. This dilemma caused the clinic's representatives to understand that the funding was not only a key source in this clinic, but could quite possibly be the determining factor to any progress made at the legislature in expanding avenues to increase access to care.

The financial hurdle of funding proponent legislative effort, as well as that of enacting legislation, had to be addressed, and legislators began to voice concern over where the funding would come from in a period of economic decline where the state was considering severe budget cuts to health care funding. As one lobbyist proponent recalled:

"Initially we were underfunded and everyone was doing a lot of pro bono work... Later [ national proponent group] found out about our efforts and helped [monetarily] with the final year of work."

That final year of legislative efforts is what created an opening for those legislators who saw the need for the new workforce model, but felt they could not support it due to budget cuts. According to one dental educator proponent:

"...the one hearing that really swayed some legislators, which was instrumental, was when we ...[received].. funding from [national stakeholder group] , and we had [proponents] from Canada come. This truly, truly was a turning point for many people at that hearing..."

*Partnerships and Coalitions:* Within the partnerships and coalitions theme, the categories of stakeholders (including risk takers and leaders), collaboration, broaden the field and communication are brought to life through the stakeholder interviews, documents and the researcher's observations. As one lobbyist proponent recalled:

"So eventually we had a group of over 50 organizations that were listed as supporters...[many of these organizations were] both a provider and a health plan providing dental services to low income populations... [as

well as] legislators... who helped make it happen. And a number of dentists who were actively involved and were vital to the success of the legislation."

As may be expected, it was the relational aspect (partnerships and coalitions built between proponent groups throughout the legislative process) that ultimately helped to pass legislation for the advanced dental therapist. As stated by a dental educator proponent:

"...there were 59 organizations at the end that signed on. Of those 59 organizations maybe just one would write a letter, one might have their lobbyists [help], and another might make calls, but I really think everybody had a part..."

The individuals interviewed for this case study all mentioned that there were 3 main groups that spearheaded the legislative efforts: the safety net coalition, the state dental hygienists' association and the proponent university. However, the group of stakeholders as a whole was broad, and those stakeholders involved varied greatly in size of organization, level of influence on legislation, type of connection they had to dentistry and reasons for supporting the role of the new dental provider. As one dental educator proponent recalled:

"...Safety net couldn't have done it alone. [State dental hygienists' association] couldn't have done it alone, without the support of [national association]... none of us could have. I think we need to keep remembering that because it really was a group effort. It really, really was."

Ultimately, the group of stakeholders which stepped forward included national foundations and organizations, state level associations, and special interest groups, as well as individuals who represented others that had something at stake (e.g., mental health facilities, disability groups, nursing associations, Head Start, elder care organizations, insurance companies, public school districts, hospital systems, community action groups and the United Way). According to one legislator proponent:

"The disability community was brought in to a larger extent... and then I started thinking about all of my colleagues, and the great thing about this issue is that every single senator has dentists and hygienists in his or her district... as we gained some momentum, we started to hear from people across the country, and we heard from people all across [the state]...I tell you this story because of the power that it has, and I think that other states could do great, great work here."

A second legislator proponent echoed those remarks:

"...As we're working through the process, one of the very deliberate things that we did... we did spend some

time thinking about...these are the obvious stakeholders right here, but then I wanted to branch out beyond that because we needed many more hands..."

The collaborative efforts that were found in data analysis to have occurred between proponent groups, both the obvious and the less-likely or less-expected instances, appeared to be key to the successful passing of legislation. Especially those proponents that came from areas outside the dental profession that attested to the great need for the new provider in the underserved locations and populations throughout the state. For those working directly within the dental community, the outside perspective and feedback of proponents outside dentistry (e.g., legislators, legislative staff and health care professionals) helped them to remove personal bias from their legislative argument and to identify a strong group of outlying proponents and supporting organizations that have direct experience with the oral health disparities of underserved populations. As observed by a lobbyist proponent:

"We tried to maintain good communication and good relationships with [bill opponents], and that was important although our relationships were probably stretched to their limits. It's important on all of these things to try not to get personal and to keep communicating because in the end what was key when it was time to compromise was the ability to recognize that and come together and in the end... [we] sat down and worked through that compromise..."

Data analysis showed that proponents focused their communication efforts on being open, honest and uplifting so as to maintain clear, accurate and non-emotion based dialogue throughout the process. Stakeholder interviews also brought to light the impact of those opposing the legislation and confusion that it brought to the issues, as one lobbyist proponent shared:

"...after that happened [a supporting dentist became an unexpected opponent] we got all of the community health center dentists together and did a briefing on what it [the bill and workforce model proposal] was... they were just getting only one side of the story and we hadn't paid attention... that made a big difference and people understood better, because through the whole process there was a lot of misinformation... about the bill...It took a lot of work to correct the inaccurate information. But that worked to our advantage because the [opposing state organization] continued to do this...and it doesn't take people long to get burned by that to stop listening to them."

Field notes of the researcher observer reflect that this miscommunication of the facts could have easily diverted the bill long and far enough that the momentum could have been lost and the heroic, and sometimes risky,

efforts of proponent stakeholders would have been for nothing. Keeping communications honest, accurate and simple was the key to progress.

*Legislative Process:* Within the legislative process theme, the categories of compromise, lobbying, toll, intimidation, controversy, semantics, mentors and rookies are brought to life through the stakeholder interviews, documents and the researcher's observations. According to one educator proponent:

"It is interesting when you look back on [the last 6 years], all these events aligned. If there is a message I could deliver to anybody initiating legislation, this is not a quick process...I've been dealing with [the] issue since October 2005 on almost a daily basis."

The legislative process of promoting, debating and negotiating the issues related to the legislation for the advanced dental therapist was a long, detailed process. It took place over the period of 2 legislative sessions, as well as 2 to 3 years of advocacy and education prior to setting the stage for legislators to understand the proposal once it was introduced as a bill. Discussion of both the positive and negative experiences related to the proponents group follows.

All stakeholders interview participants agreed that year 1 of the legislative process was filled with education and advocacy for the access to oral care issue in order to gain momentum and support for the new provider being proposed. As a result, it was important to have one or more legislators to "champion" the cause. A dentist proponent recalled:

"...I do not know how they got [legislator proponents] to champion the cause, but I do know that [senator] frequented those listening sessions they'd done around the state and that the number one complaint...was the lack of dental care...that's where her interests lay..."

After gaining legislators willing to author a bill for the proponents group, a strategy was developed that would help the bill gain momentum, according to one lobbyist proponent:

"...In developing the strategy for the legislation we thought it was very important to keep the focus on access and on the safety net system of programs and health care providers that serves low income and the disadvantaged populations... So the safety net took a lead in the public visibility so it wouldn't be a particular stakeholder group... but rather a broader coalition of many different stakeholder groups..."

Members of the proponents group visited senator and representative district hearings and health care forums to testify on the oral health disparities present in the

state and the need for increased access to oral health care. As the researcher observer's field notes describe, opposition was immediately met as the state dental association sent a letter to dentists and state legislators that positioned the new dental provider model as unsafe and self-serving for dental hygiene. Many grassroots efforts were formed and implemented as a way of clarifying the facts from fiction. In field notes, the researcher-observer notes that mailings were sent to dental hygienists licensed in the state and residing in key legislative districts, and all dental education programs in the state received a DVD on dental lobbying, pointers on contacting legislators and Q&A sheets on the hygienist-therapist model and the dental needs of Minnesotans.<sup>30</sup> According to one dental educator proponent:

"I think it was constantly, on a daily basis, just informing..., addressing issues, ...myths versus facts, but I think that was key. If one myth would surface we'd come up with the facts for that, then another myth would surface. And I think that was very key that we stay focused and on message."

Once the bill was officially read (first reading), at the start of the legislative session, committee hearings took place to hear the bill and allow for testimony from both the proponent and opponent groups. By the end of the first legislative session, the bill was heard in approximately 10 different committee meetings. As one lobbyist proponent recalled:

"Throughout the process there were 3 or 4 times when we were at a point at which we could have lost the bill or kept the bill, and managed to find a way through all those things."

In April 2008, the hygienist-therapist proponents' bill was accepted in to the Omnibus Higher Education bill (SF 2942) and was established with language as the Oral Health Practitioner (OHP). Changing the name from the ADHP to the OHP was a compromise in order to move forward with the legislation with less opposition as the name did not include the direct relation to dental hygiene. Opponents did not want the name dental hygiene to be part of the new provider's title. In fact, stakeholders interviewed for this study mentioned repeatedly that throughout the legislative process, any use of the phrase "dental hygiene" became very inflammatory. A legislator proponent stated that:

"I didn't really have a lot of preconceived notions...I was new to this... whether it was called the ... or ... I suggest we just leave a blank because that was seemingly a stumbling block...we could have gotten derailed with a detail like that...no matter what we called it I wasn't going to get the dental association on board."

The above statement not only highlights the political

climate that surrounded this perceived "threat to dentistry," but also emphasizes the fact that many times legislators get involved in legislation that is not their area of expertise, but an area that involves a committee they serve on or an issue that impacts the district they represent. From the perspective of someone outside dentistry, the name of the new dental provider was not what was important - it was the oral health disparity that needed to be addressed. And for that reason, having a "rookie" legislator involved aided in the need to keep perspective. As stated by a legislator proponent:

"...The first bill in the first year was the end result...I would say, generally speaking in year one we had your basic stakeholders."

The governor signed the hygienist-therapist bill in to law with a few requirements still to be met. The key points highlighted in the law included:

- Limiting oral health practitioners to practice in safety net settings and serving low-income, uninsured and underserved populations
- The state department of health would be required to convene a work group to develop recommendations and report back to the legislature the following year on the topics of scope of practice, licensure and regulatory requirements, education programs and curricula, dentist supervision requirements and other issues
- The new provider would be required to have a written collaborative management agreement and be supervised by a state-licensed dentist currently practicing in the state

Several observations were made by various proponents:

- Legislator proponent - "First of all, the workgroup was defined in law, and I would highly recommend that...it's the most prescriptive piece of legislation that I have ever worked on. Very prescriptive."
- Dental educator proponent - "The workgroup was mandated by the legislature to meet from August through December. Our charge was to bring recommendations back in January 2009...to the legislature..."
- Legislator proponent - "The charge of the workgroup was to figure out how this was going to happen...not if. And I went to the workgroup on more than one occasion to remind them of that...they were not all on the same page, even though it was statutorily defined they were still having conversations about could or should we do this...they didn't have purview or jurisdiction over that discussion..."
- Dental educator proponent - "The key was [in the workgroup]...it ended a lot of times with votes 7 to 6...it was a good process in some ways, though con-

sensus wasn't met on every issue...it really defined the issues and we knew what we were going to be fighting for in 2009- supervision and scope of practice were going to be huge..."

- Lobbyist proponent - "[The workgroup] did a lot of hard work on the details of how you would create a licensing system, what scope, what services...so the work needed to be done..."

The workgroup concluded their work after its 13 members met a total of 8 times to develop recommendations to report back to the legislature. Through field notes of the researcher observer, the workgroup sessions were described as heated conversations with both the opponent and proponent opinions being shared openly and sometimes with great debate. Mediators were frequently required to cut off discussion as it easily continued on without consensus. While the focus of the workgroup was meant to be on the new legislation's hygienist-therapist, the opponents in the workgroup began to discuss movement toward a different, or additional, workforce model. Many assumed this new development would result in 2 different provider proposals to legislators in the following legislative session: The dental therapy (DT) model as utilized in over 50 other countries as an entry-level dental provider, and the dental hygienist-based OHP (later renamed the ADT) with the same basic education of the dental therapist, but with additional education requirements and with an expanded scope of practice and less restricted supervision (similar to the dual licensed dental hygienist/dental therapist in the U.K.).<sup>21</sup>

The final workgroup report was submitted to the legislature before the start of the next year's legislative session with recommendations for further review. As described above, these recommendations were not made unanimously by the enter committee, but with very close voting records. Due to the lack of unanimity, and subsequent stalemate of conversation within the workgroup, a dental educator proponent reported:

"...I remember the last meeting...we cancelled...we did it all by e-mail because [the moderator] said "I want to release you from this hell." And it truly was. It truly was."

As one legislator proponent recalled:

"[The first legislative session] answered the question of whether to establish a new oral health practitioner... it did not answer the how, and that's why we had the workgroup [to recommend] the how, but it really didn't end the controversy. So in January [of the second year] we introduced the bill, but [later] there were actually two bills that came forth..."

Things began to move very quickly at the start of the second legislative session. The OHP bill was introduced

with the recommendations made by the workgroup, and field notes from the researcher-observer include letters from the state dental association that shared their position as being committed to see the legislation fail. During this time, many dentists voiced their opinions on the topic and the fact that not all dentists' opinion aligned with the position of their professional association. As one dentist proponent stated:

"And we get drowned out because we're not the ones with the big money, giving money to the legislators...To me it was so disheartening when my fellow [specialty] dentists could not even understand the concept of children with unmet needs..."

However, other dentists had to decide whether the cause they were representing was worth the controversy they might stir up within their own professional roles. As one lobbyist proponent recalled:

"We had a disappointment in [dentist and educator] ...he was part of the oral health committee that recommended doing this, and he was an advocate for it, testified on our behalf at the first couple of hearings, and then we had a legislative committee hearing...[and] he said, 'I have to tell you that I've decided to move to the opponents' side. I'm going to be testifying against the bill...it's just become too divisive and I don't think the dentists are ready yet...It's not that I don't believe this is a worthwhile thing to do, it's just that this is creating so much dissention in the dental community and people are getting heated up about it.' He couldn't support it and so he began testifying against the bill at that point. ...It was very disappointing. I have the greatest respect for him and I know how much pressure he was under. I also believe he thought he was doing the right thing... but regardless the pressure from the dentists led him to switch sides and that was very disappointing... I think that it illustrates what was happening."

These dentists were described in interviews as one of many groups that took a lot of heat and harassment throughout the legislative process.

Soon after, the second bill was introduced by the state dental association and another state university with an existing dental education program as well. Advocates began to voice their interests and/or concerns about the bills and additional stakeholders began to emerge. According to one dentist proponent:

"...The other stakeholder was the university. But what was interesting when we first started to push this forward is that they were against it. Then within a very short amount of time there was a complete turnaround... once they realized that the tide of support was going the way of the ADHP, the OHP,...all of the sudden it was, 'Wait a minute. Wait a minute. It's going to happen and we're



not going to be a part of it. So we need to be part of it.”

Another dentist proponent commented on the inclusion of the university as a stakeholder:

“...Certainly the university coming on board gave it more strength. Even though they were looking at a different model, it... created the situation where, okay, this major academic university [is interested]...how can we do this and compromise with the dental association...?”

The opponents’ bill had both similar and differing aspects in its scope of practice, level of supervision, and education requirements. As noted by two legislator proponents:

“...There were a lot of different names, a lot of the bill was similar, but really the devil was in the details and clearly the [state dentist association] proposal was not friendly to... general supervision”

“... In committee the night that the two bills were presented for the first time, I accepted an amendment to put the [opponents’] bill onto my bill. Okay? ...I had it, with my name on it. And never in their wildest imagination did they ever think that I would accept that...or ask for it...that was great that we did that. I had everything... it’s all a process. And so, by accepting that amendment, to my colleagues that were supporting the [opponents’] position...I had them... And to the colleagues that were supporting the hygienists’ position... I had them. I had everybody arguably. So that was a pivotal moment.”

At this point, both provider models moved forward under one bill. For the second legislative session, the bill was heard in many committee meetings. As one lobbyist proponent recalled:

“And then they went to conference committee, so that’s where the final negotiations occurred. Everybody was lobbying heavily and [legislator] was the chair of the higher ed committee...and the turning point was when we were able to persuade [him] to support our position... He likes [Proponent University] a lot, they were pretty influential on that [decision]...he just also came from a rural area. He’s seen all the access issues...”

Once the committee’s intent was clear, the opponents group quickly agreed to achieve a level of compromise. As recalled by three lobbyist proponents:

“After that announcement [conference committee accepting conference report] I walked out in to the hall and [opponent lobbyist] came up and said ‘You know, I think the time has come. We need to go and figure out how to do this.’”

“Much of the compromise was about details and ter-

minology, because the legislators had made it pretty clear that they were supporting primarily the Senate proposal which was what the Proponents Alliance wanted. So some of the changes were... take the word diagnosis out and put in oral evaluation and assessment... Provide medication rather than prescribe. Affirming the two levels of dental therapists ... Affirming dentist supervision and making it clearer that extractions of permanent teeth could not be done without prior authorization of a dentist...”

“And by this time the [state-level dental association] had put a spin on it that it was a positive thing and they’d won big in the compromise ...and they’ll never live it down because we still have the press announcement where they said... ‘We’re very happy with the compromise. We know patients will be protected.’”

This coming together of lobbyists, representing the proponents and opponents groups, was the final negotiation that allowed the bills to settle and for both parties to agree to move forward and wait on a vote from the legislature. However, the negotiations were a key factor to legislators agreeing to back the bill once they saw consensus between parties. All stakeholders interviewed for the case study agreed that one great asset to the lobbying process included the fact that because many organizations were involved, there were also many lobbyists that represented these groups who were willing to help carry the load. As one educator proponent said:

“...I really think it boils down to it was the right thing to do. Legislators were tired of hearing about it. It was all about access...it was about the patient.”

A few topics, yet to be discussed, centered on the categories of controversy, intimidation and battles over semantics. Through data analysis these categories emerged and were emphasized by those interviewed to have left a personal toll on many who participated in the legislative process. One legislator proponent shared their thoughts:

“I was very pleased at the progress that we had made in that first legislative session, but I felt... like I don’t know if I can carry this again. I didn’t think about giving up the bill. I was thinking ... I am tired and I was heavy, so let’s think about who can help us.”

Not only was this process wearing, but it also carried a professional toll, one that did not just affect the primary individual involved. A stakeholder interviewed stated that the proponents group also had members receiving varying levels of pressure from others in their profession, which caused the proponents group to step back and make sure every member was comfortable with each step as they moved forward. According to one legislator proponent:

"I had a Republican coauthor, who bailed on us in the second year..And I was shocked..I went to my colleague and I asked why? I thought there was a mistake because I knew this senator believed in the legislation. And the fact was simply that [legislator] said it got too hot. The heat was too hot... I said, 'The heat was too hot from what? From those twelve dentists in your district? You have 67,000 constituents..' I think that there is that kind of influence out there as well, and again I think that it's a testament to again making sure that you really have a champion. And that to other states, that they are supporting their champion through the process, every step along the way. And... in their home district because they need it."

Intimidation also played a role that contributed to the toll experienced by proponents of the bill, as one dentist proponent recalled:

"And the professional groups such as [dental specialty] were vociferous in terms of email and telephone calls, but they didn't show up at the table. They were like the paper tiger. They were outraged, and I advised the group at one of the meetings that...they should tone down the rhetoric because... just being rude wasn't painting us in a very good light...that negativity from the dental profession turned the legislators against dentists."

An educator proponent echoed those remarks:

"I had received over 7,000 emails during 2008 and 2009...It was like, 'I'm doing the very best that I can..' And I did that morning, noon and night. Besides working."

The toll and intimidation issue reached beyond just dental professionals, it affected those politically aligning themselves with the issue as lobbyists and legislators, and even their families, despite their feelings of it being "the right thing to do." Several proponents recalled their experiences:

Educator proponent - "How tough was he [proponent lobbyist] to put up with a lot of pleasing all parties...it got personal for a lot of people. There were a lot of negative phone calls... there was a lot of pressure being put on them...there [were] people and families...and jobs on the line."

Legislator proponent - "The [national association opponent] took out a huge ad campaign, and they had print ads... and radio ads, and they were all over my home district...it was a full page ad in the paper...So I got home, walk in, and [my son] has the newspaper with the full page ad, 'Call [legislator proponent]..'

"[The] full page ad's out on the kitchen table and he's standing there looking at it and he goes, 'Oh mom,...

What are you going to do?..' I hadn't seen the ad..., but I looked at it and I said, 'You know ...don't you worry... we're fighting for people who aren't at the capitol every day.' And that's how I answered [him] and then I told my husband we wouldn't have the radio on at all that weekend because the waves were just full of 'call Senator..' and I didn't want my kids to hear that."

Despite the accusations and intimidation, the proponents group rallied together to support the cause and the people involved. According to one lobbyist proponent:

"In fact, there was sort of a phenomenon going on that people really sort of got in to this personally, you know? It was like, David and Goliath. Even though it might have been a small issue for their organization they took it on as a personal campaign, so we probably had a dozen lobbyists that were all working on this at different times..."

## Discussion

The National Call to Action, published in 2003, identified the need for an enhanced oral health workforce to address the underserved and unmet oral health needs of epidemic proportions in the U.S.<sup>13</sup> This case study has attempted to examine the complex phenomenon that is outlined by one state's unique approach to introducing new workforce models and the legislative process surrounding the enactment. The unique adoption of 2 oral health care workforce models in the legislation, one that allows for entry in to the profession at a baccalaureate level and a second model that builds on an existing oral workforce model, (baccalaureate dental hygiene) to develop a graduate level provider with expanded duties and general supervision. These new workforce models are intended to expand access to oral health care services by allowing providers to work in non-traditional settings, therefore reaching individuals with oral health disparities. As previously discussed by Nash, the therapy model has been introduced around the globe as both an entry-point and end-point to the needs of the many people who lack access to dental care in a broken system.<sup>18</sup> These findings have been confirmed through a recent Kellogg report that explored the impact of the DHAT in Alaska and indicate the increase in access to quality dental care created by this new provider.<sup>31</sup>

There are numerous states currently pursuing legislation that would expand access to dental care. The results of this qualitative study may serve to inform proponents of the ebb and flow of the legislative process when introducing legislation and to illuminate lessons learned. When broadly considering the results of the study, there are "Lessons Learned" that clearly arise for readers to consider:

- Legislation involving new workforce models is not a quick process
- Find a champion in the legislature and support them in their home district
- Educate and involve the public

Do not assume a colleague is a proponent/opponent just because of what they do or where they work. Find professional proponents in each legislative district to connect to legislators and share their personal passion. An additional lesson learned was the importance of watching and learning from other emerging workforce models. There is much to be learned from what initiatives have already occurred or are currently developing in other states.

In this qualitative case study, stakeholders interviewed described perceptions of the future impact of the advanced dental therapist. These perceptions are consistent with the recent PEW study which showed up to a 52% increase in office productivity and profit when adding a hygienist-therapist to the practice of a solo dental provider.<sup>26</sup> The enacted legislation requires that a report be submitted to the legislature on the success of the workforce model after the initial workforce has been practicing for 2 years. A lesson to be applied to this study is that it takes many years or even decades for the significance of a new workforce model's impact to be documented and that this new workforce model will be no different.<sup>31,32</sup>

A phenomenon identified while conducting this case study was the passion that developed across proponent individuals and groups to rally around the oral health disparities existing in their state. This passion has been shown in similar expanded practice enactments as a significant source of momentum to initiate and sustain access to care efforts in state legislation. Similar studies looking at alternative workforce models have shown passion as one of the driving forces to move people to action.<sup>32,33</sup> Concomitantly, the funding from national organizations has provided the support needed to allow proponent groups to pursue this issue in additional states.

The limitations of the study should be mentioned prior to conclusion. The role of the researcher as a participant is credibly accepted within the qualitative method. However, this lends itself to the potential for bias as

the opinions and experience of the researcher come as part of their perspective on the case study. Conversely, one of the greatest strengths of this qualitative case study approach is the richness and the depth of exploration and descriptions of the phenomenon from which much can be learned. Additionally, while the qualitative research method allows for understanding about individual cases and subjects, is not intended for broader generalizations.

## Conclusion

The results of this qualitative case study serve to inform professional practice and decision making in both clinical and policy realms. The legislative process shared here should provide other advocates of access to oral health care an example to be applied and tailored to similar efforts across the country. Passion leads to advocacy and the future elimination of the oral health care crisis in the U.S. When it is the right thing to do, and the right issue to support, people will come together to speak for those who don't have a voice.

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## References

1. Oral health in America: a report of the Surgeon General. *J Calif Dent Assoc.* 2000;28(9):685-695.
2. Slavkin HC. The failure of dentistry's social contract with America and California's search for legislative solutions? *J Dent Educ.* 2003;67(10):1076-1077.
3. Centers for Disease Control. Behavioral Risk Factor Surveillance System (BRFSS). National Center for Chronic Disease Prevention and Health Promotion. 1995.
4. Gift HC, Reisine ST, Larach DC. The social impact of dental problems and visits. *Am J Public Health.* 1992;82(12):1663-1668.
5. Davis EE, Deinard AS, Maiga EW. Doctor, my tooth hurts: the costs of incomplete dental care in the emergency room. *J Public Health Dent.* 2010;70(3):205-210.
6. United States Government Accountability Office. Efforts under way to improve children's access to dental services, but sustained attention needed to address ongoing concerns. 2010.
7. Bath A. Lack of dental coverage send patients to ER for pain. USA Today. 2012 January 20.
8. Pettinato ES, Webb MD, Seale NS. A comparison of Medicaid reimbursement for non-definitive pediatric dental treatment in the emergency room versus periodic preventive care. *Pediatr Dent.* 2000;22(6):463-468.
9. A costly dental destination: hospital care means states pay dearly. The Pew Charitable Trusts [Internet]. 2012. Available from: [http://www.pewtrusts.org/our\\_work\\_report\\_detail.aspx?id=85899372468](http://www.pewtrusts.org/our_work_report_detail.aspx?id=85899372468)
10. Cohen LA, Bonito AJ, Akin DR, et al. Toothache pain: a comparison of visits to physicians, emergency departments and dentists. *J Am Dent Assoc.* 2008;139(9):1205-1216.
11. Trzeciak S, Rivers EP. Emergency department overcrowding in the United States: an emerging threat to patient safety and public health. *Emerg Med J.* 2003;20(5):402-405.
12. The National Report Card on the State of Emergency Medicine. American College of Emergency Physicians [Internet]. 2006 January. Available from: <http://www.acep.org/assets/0/16/648/1994/00FA9DFA-9B89-4DA8-A3D8-5FBD37DD858D.pdf>
13. U.S. Department of Health and Human Services. A national call to action to promote oral health. Public Health Service, Centers for Disease Control and Prevention and the National Institutes of Health, National Institute for Dental and Craniofacial Research. 2003.
14. Bailit H, Beazoglou T, Demby N, McFarland J, Robinson P, Weaver R. Dental safety net: current capacity and potential for expansion. *J Am Dent Assoc.* 2006;137(6):807-815.
15. Berenson A. Boom times for dentists, but not for teeth. New York Times. 2007 October 11; Business.
16. Two kinds of dentist shortages fuel one major access problem. The Pew Charitable Trusts [Internet]. 2008. Available from: [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/State\\_policy/children\\_dental\\_shortage\\_access\\_brief.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/State_policy/children_dental_shortage_access_brief.pdf)
17. Nash DA, Friedman JW, Kardos TB, et al. Dental therapists: a global perspective. *Int Dent J.* 2008;58(2):61-70.
18. Nash DA. Will today's dental public health workforce meet tomorrow's needs? National Oral Health Conference [Internet]. 2007 April 30. Available from: <http://www.nationaloralhealthconference.com/docs/presentations/2007/0430/David%20Nash%20Opening%20Plenary%20NOHC%20Speech.pdf>
19. Sell C. The Rise and Rise of PCDs. *Vital.* 2005;2(3):16-18.
20. The Dental Auxiliaries (Amendment) Regulations 2002 No. 1671. UK Legislation [Internet]. 2002. Available from: <http://www.legislation.gov.uk/ukxi/2002/1671/contents/made>
21. Dollins HD, Gadbury-Amyot CC. The United Kingdom dental therapist: lessons learned. *Access.* 2008;22(3):6,8,10,12,14,16-19
22. Ward P. The changing skill mix - experiences on the introduction of the dental therapist into general dental practice. *Br Dent J.* 2006;200(4):193-197.
23. Forrest JL, Gurenlian JR. Increasing access to quality dental hygiene care. An educational model. *J Dent Hyg.* 1989;63(5):238-241.

24. Beach MM, Shulman JD, Johns G, Paas JC. Assessing the viability of the independent practice of dental hygiene--a brief communication. *J Public Health Dent.* 2007;67(4):250-254.
25. Mitchell TV, Gadbury-Amyot CC, Overman PR, Peters R. The impact of Kansas House Bill 2724: perceptions of Kansas dental hygienists and dental assistants. *J Dent Hyg.* 2003;77(4):233-244.
26. It takes a team: how new dental providers can benefit patients and practices. The Pew Charitable Trusts [Internet]. 2010 December 6. Available from: [http://www.pewtrusts.org/our\\_work\\_report\\_detail.aspx?id=62353](http://www.pewtrusts.org/our_work_report_detail.aspx?id=62353)
27. Guba EG, Lincoln YS. *Naturalistic Inquiry.* Newberry Park, CA: Sage; 1985.
28. Ozar DT, Sokol DJ. *Dental ethics at chairside: professional principles and practical applications.* 2nd ed. Washington D.C.: Georgetown University Press; 2002.
29. Recognizing nursing's independent license: prescriptive authority for APNs. *Mich Nurse.* 2001;74(3):suppl 13-14.
30. Dollins HE, Ettus-Johnson P. *Legislation in dental hygiene.* Kansas City, MO: University of Missouri-Kansas City; 2004.
31. Wetterhall S, Bader JD, Burrus BB, Lee JY, Shugars DA. Evaluation of the dental health aide therapist workforce model in Alaska. Final report. Research Triangle Park, NC: W.K. Kellogg Foundation; 2010.
32. Battrell AM, Gadbury-Amyot CC, Overman PR. A qualitative study of limited access permit dental hygienists in Oregon. *J Dent Educ.* 2008;72(3):329-343.
33. Delinger JE. A qualitative case study of extended care permit dental hygienists in Kansas [thesis]. Kansas City (MO): University of Missouri-Kansas City; 2011.

## Extending Oral Health Care Services to Underserved Children through a School-Based Collaboration: Part 3 - A Cost Analysis

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### Introduction

Dental care has recently been recognized as the most prevalent unmet health care need for children in the U.S. While the issue is not often in the spotlight, millions of American adults and children lack access to preventive, routine dental care.<sup>1,2</sup> If the challenges that underserved and vulnerable populations encounter when trying to access oral health care are not addressed, the burden of oral disease these populations experience will continue to grow.<sup>3</sup> Furthermore, the cost and impact associated with health disparities place complex economic burdens on the nation. A report on the economic burden of health disparities in the U.S. estimated that 30.6% of direct health care costs for African Americans, Asian Americans and Hispanics from 2003 to 2006 were excess costs associated with health inequalities.<sup>4</sup> Premature loss of life, increased burden of disease and inadequate access to quality care continue to pervade the health care system.<sup>4</sup>

Eliminating health disparities remains a monumental challenge. According to a 2011 survey conducted by Lake Research Partners for W.K. Kellogg Foundation, those most likely to not have a place to receive regular dental care include those with incomes less than \$30,000, who lack dental insurance, who have a high school diploma or less education, or who are Latino or African American.<sup>1</sup> The current structure of dental practice further complicates access to care issues. Unlike medical care, most dental services are provided in private practices with 1 or 2

### Abstract

**Purpose:** The purpose of this manuscript was to conduct a cost analysis of the Miles of Smiles Program, a collaboration between the University of Missouri-Kansas City School of Dentistry and the Olathe School District in Kansas. This preventive program was implemented to improve the access to oral health care for low income children within the school district.

**Methods:** An inventory list and de-identified patient records were used to determine the costs associated with operating the program to serve 339 elementary school students during the 2008 to 2009 school term. Costs related to equipment, supplies and personnel were included. The costs were then compared to the amount of Medicaid reimbursement obtained for the services provided. Additionally, the cost of operating a similar program, if staffed by dental professionals rather than supervised dental hygiene students, was estimated.

**Results:** The cost of operating the program during the 2008 to 2009 school term was \$107,515.74. The program received Medicaid reimbursement for approximately 1.5% of the total operating cost of and approximately 6.3% of the total billable services, however, challenges with submitting and billing Medicaid claims for the first time contributed to this low rate of reimbursement. If a similar program that utilized dental professionals was implemented and treated the same number of patients, the cost would be approximately \$37,529.65 more due to higher expenses associated with personnel and supplies.

**Conclusion:** The program is not self-sustainable based on Medicaid government-funded insurance reimbursement alone, and therefore continuous external sources of funding or a change in the program design would be necessary for long-term sustainability of the program.

**Keywords:** access to care, dental hygiene education, community-based dental education, dental care for children, oral healthcare for the underserved, portable equipment, school-based oral health, cost analysis, dental medicaid program

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oral health care providers, and are often located in metropolitan areas.<sup>2</sup>

### **Strategies to Address Access and Disparity Issues in Oral Health Care**

Upon reviewing evidence that indicates millions of Americans have unmet oral health needs due to barriers in access to care, the Institute of Medicine and National Research Council committee prepared the "Vision for Oral Health Care in the United States," outlining how public and private providers should address oral health care for these populations. The vision stated that "to be successful with underserved and vulnerable populations, an evidence-based oral health care system will: eliminate barriers that contribute to oral health disparities, prioritize disease prevention and promotion, provide oral health services in a variety of settings, rely on a diverse and expanded array of providers competent, compensated, and authorized to provide evidence-based care, include collaborative and multidisciplinary teams working across the health care system, and foster continuous improvement and innovation."<sup>3</sup>

The findings and conclusions from the Institute of Medicine and National Research Council's report on improving access to oral health care for vulnerable and underserved populations support the fact that no single setting of care will meet the needs or overcome the barriers of these populations.<sup>3</sup> For several years, researchers have suggested that alternative practice models could meet the oral health needs of target populations, demonstrating a role for both public and private sectors to get involved.<sup>5-7</sup>

### **School-Based Safety-Net Clinics**

When considering access to care issues for low-income and minority children, the School-Based Safety-Net Clinic model has been suggested as a viable option. This model of providing care for children in the community in which they live can provide quality health care services by reducing financial, language, familial and cultural barriers.<sup>8</sup> If school based safety net clinics are to be considered an effective method for delivering preventive dental care to target populations, the issue of funding and financial support should be explored. A 1997 investigation conducted by Albert et al evaluating school-based oral health care programs found that 27% of the clinics were sponsored by health departments, 27% by hospitals/medical centers, 27% by community-based organizations and private agencies, 17% by community health centers, and 2% from other sources.<sup>9</sup>

Existing models of sponsorship and collaboration include the Forsyth Kids program, a Massachusetts school-based caries prevention program sponsored by the Forsyth Institute. The institute developed the program to ensure that it meets national oral health goals for high risk populations.<sup>10,11</sup> Another school-based program, The Apple Tree Dental organization, utilizes a mobile delivery system that travels to patient populations with special access needs and provides a variety of dental services. The program is supported by individual donors, foundation grants and corporate sponsors.<sup>12</sup>

As the dental hygiene scope of practice increases with changes to supervision requirements, underserved populations may benefit from services provided by dental hygienists in school-based clinics. An example is a bill passed in Kansas in 2003 that allows dental hygienists to earn an Extended Care Permit (ECP) to provide a wide range of preventive services in community settings under the sponsorship of a dentist. This permit allows dental hygienists to provide preventive services without being under the direct supervision of a dentist if the services are provided to vulnerable populations and/or in public health or community-based clinics.<sup>13</sup> School-based safety-net dental clinics utilizing an expanded scope of practice dental hygienist, such as an ECP dental hygienist, appear to be a promising solution to address access to care issues related to personnel and cost of care. However, one of the key considerations in making these clinics sustainable and replicable is whether additional financial support from an external source is necessary to maintain program viability.

### **The Miles of Smiles Program**

Miles of Smiles is a collaborative program between the University of Missouri-Kansas City (UMKC) School of Dentistry, elementary schools within the Olathe School District (located in Olathe, Kansas – a suburb of Kansas City), an Extended Care Permit Dental Hygienist (ECP-I), and the REACH Healthcare Foundation. These organizations partnered together to provide preventive oral health services to disadvantaged children in 4 schools with a high proportion of low income population.<sup>14,15</sup> The services were provided 2 days per week by senior dental hygiene students enrolled at the UMKC School of Dentistry and are supervised by a faculty member who currently holds a Kansas dental hygiene license and an ECP-I. The ECP-I dental hygiene faculty member serves as the project manager on the Miles of Smiles project.

The program began during the 2008 to 2009 school term. During the first year of operation, 389

students were enrolled in the program, and services were provided to 339 students. The demographic information for the participants is documented in Table I. More information about the operation of the Miles of Smiles Program is provided in part one and part two of this series.<sup>14,15</sup>

### Purpose and Research Questions

The purpose of this study was to conduct a thorough cost analysis of the Miles of Smiles program during the 2008 to 2009 school year. The following research questions guided the analysis:

- What are the costs of operating the program?
- How does the cost of operating the program compare to the amount of Medicaid reimbursement received for the services provided?
- What would a similar program cost if staffed by paid dental professionals only?

## Methods and Materials

### Data Sources

Data related to the services provided in the Miles of Smiles program during the 2008 to 2009 school term were obtained from an existing database. The database was previously created by extracting de-identified information from the electronic patient records. A list of the equipment and supplies necessary to run the program were provided by the program manager and the prices of all items listed were obtained by contacting sales representatives of dental supply companies.

### Data Compilation

To begin the analysis of the direct costs associated with the program, all equipment and supplies necessary to run the program were separated into 2 categories: fixed costs and variable costs. Unless otherwise noted, all durable equipment and instruments were assumed to have a useful life of 5 years and were depreciated over the same period using the straight-line depreciation method.

The researcher observed the daily operation of the program for 3 days to determine the average quantities of disposable supplies and materials needed for each procedure. This information was utilized to prepare standard cost profiles associated with each billable service provided. Since the design of the Miles of Smiles Program utilizes supervised senior dental hygiene students to provide the services as part of their service-learning curriculum, the cost associated with the program manager's salary and benefits was the only direct personnel cost for this

Table I: Demographic Information of 2008 to 2009 Miles of Smiles Program Participants

Category	Number (n)	Percentage (%)
<b>Age</b>		
0 to 5 years	4	1
6 to 8 years	165	42.4
9 to 14 years	215	55.3
Unknown	5	1.3
<b>Gender</b>		
Male	213	54.8
Female	176	45.2
<b>Race/Ethnicity</b>		
Hispanic	193	49.6
Caucasian	117	30.1
Black	49	12.6
Asian/Pacific Islander	19	4.9
Two or More Reported	9	2.3
Unknown	2	0.5

program. The benefits were determined using the customary formula of 35% of the annual salary.<sup>16</sup>

Facilities and Administration cost equal to 50% of the direct costs were added to fully account for indirect operating costs. The indirect operating cost rates are based on the policies of the UMKC Office of Research Services.<sup>16</sup> Indirect operating costs include expenses such as utilities associated with operating the program, storage for the equipment, transportation of equipment to the various sites, and data management for statistical purposes and Medicaid claims. Personnel within the Patient Accounts office at the UMKC School of Dentistry assisted with the program by submitting and processing all Medicaid claims for patients treated within the program.

The amount of Medicaid reimbursement received for each patient encounter was also documented in the database and utilized to make the comparisons. In addition, the average hourly salary of dental hygienists in the state of Kansas was obtained from the Bureau of Labor Statistics to compare the cost of this program to a similar program staffed by dental professionals only.

## Results

### Operating Costs

The fixed costs for the 2008 to 2009 school year were determined from the program inventory list. Because all equipment except certain dental hygiene instruments were assumed to have useful lives of 5 years, annual cost was determined by dividing the purchase/market price of each by 5. Given the



Table II: Fixed Costs – Equipments and Instruments

Equipment and Instruments	Quantity	Price Per Unit	Total Price	Life Span (in years)	2008 to 2009 Cost
Portable operatory	2	\$4,355.00	\$8,710.00	5	\$1,742.00
Portable light	2	\$1,104.00	\$2,208.00	5	\$441.60
Portable chair and carrying case	2	\$3,270.00	\$6,540.00	5	\$1,308.00
Operator Stool	4	\$574.00	\$2,296.00	5	\$459.20
Operator Stool - Carrying Case	4	\$190.00	\$760.00	5	\$152.00
Handheld Extraoral X-ray	1	\$7,495.00	\$7,495.00	5	\$1,499.00
Positioning Stand w/ Remote Activation	1	\$750.00	\$750.00	5	\$150.00
Carrying Case	1	\$465.00	\$465.00	5	\$93.00
Digital Scanner, Eraser, and Phosphor Plates	1	\$19,000.00	\$19,000.00	5	\$3,800.00
Child-size Lead apron	2	\$77.99	\$155.98	5	\$31.20
Laptop Computers w/ software	4	\$2,400.00	\$9,600.00	5	\$1,920.00
Printer	1	\$249.00	\$249.00	5	\$49.80
Ethernet cord	1	\$8.99	\$8.99	5	\$1.80
Extension cord/Surge Protector	2	\$18.00	\$36.00	5	\$7.20
Rubbermaid organizers	6	\$37.00	\$222.00	5	\$44.40
Rubbermaid storage totes	10	\$10.00	\$100.00	5	\$20.00
Autoclave w/ cassette	1	\$4,299.99	\$4,299.99	5	\$860.00
Sterilization Maintenance/Service and Strips (monthly)	12	\$16.67	\$200.04	1	\$200.04
Ultrasonic Cleaner w/ powder	1	\$349.99	\$349.99	5	\$70.00
Child Blood pressure cuffs	2	\$109.00	\$218.00	5	\$43.60
Stethoscope	2	\$5.99	\$11.98	5	\$2.40
Ultrasonic	2	\$2,629.00	\$5,258.00	5	\$1,051.60
Ultrasonic inserts (sets of 3 S,L,R)	4	\$409.00	\$1,636.00	1*	\$1,636.00

\*Life span determined by contacting manufacturer and determining the average lifespan of instruments/cavitron inserts used 2 to 4 times per week

amount of expected use in the program, the dental hygiene instruments were expected to last approximately 1 year, therefore, the entire purchase price of all instruments was included in the calculation. The sum of these prices totaled \$19,990.61. This figure represents the total fixed costs for the Miles of Smiles Program for the 2008 to 2009 term (Table II).

The variable costs were determined from the standard cost profiles for each billable procedure (Table III). The majority of the patient encounters were multi-procedure encounters, therefore, the procedure-specific standard cost profiles were combined to represent the expense for the entire encounter. The number of each multi-procedure encounter performed was then multiplied by the cost per encounter to determine the total cost associated with disposable supplies (Table IV).

The total direct cost associated with operating the Miles of Smiles Program during the 2008 to 2009 school term was determined by adding the fixed and variable costs of equipment and supplies and personnel expenditures, totaling \$71,677.16 (Table V). The total direct cost was then multiplied by 150% to account for the standard Facilities and Administration Rate, and therefore calculate the total costs associated with operating the program. The total indirect costs were \$35,838.58 (Table V). Therefore, the total cost associated with operating the Miles of Smiles Program during the 2008 to 2009 school term was \$107,515.74 (Table V).

### Medicaid Reimbursement for Services Provided

The Miles of Smiles Program provides services to any child that qualifies for the Free and Reduced

Table II: Fixed Costs – Equipments and Instruments (continued)

Equipment and Instruments	Quantity	Price Per Unit	Total Price	Life Span (in years)	2008 to 2009 Cost
Slow speed handpieces	6	\$785.00	\$4,710.00	5	\$942.00
Roto Quicks handpieces	3	\$210.00	\$630.00	5	\$126.00
Napkin Clip/Metal chain	10	\$4.49	\$44.90	5	\$8.98
Mirror (price figured by adding handle + mirror)	10	\$4.71	\$47.10	1*	\$47.10
Shepherd's Hook Explorer	10	\$12.99	\$129.90	1*	\$129.90
11/12 Explorer	10	\$16.99	\$169.90	1*	\$169.90
Nebraska Sickle Scaler	10	\$32.99	\$329.90	1*	\$329.90
204 S Posterior Scaler	10	\$32.99	\$329.90	1*	\$329.90
Columbia 13/14 Curette	10	\$32.99	\$329.90	1*	\$329.90
Air/Water Syringe tips	10	\$6.15	\$61.50	1*	\$61.50
Gracey 1/2 Curette	3	\$32.99	\$98.97	1*	\$98.97
Probe	3	\$21.99	\$65.97	1*	\$65.97
Curing light Unit	4	\$494.99	\$1,979.96	5	\$395.99
Intraoral Camera Dock	1	\$2,265.00	\$2,265.00	5	\$453.00
Intraoral Camera	1	\$3,815.00	\$3,815.00	5	\$763.00
Digital Camera w/ lenses and flashes	1	\$499.00	\$499.00	5	\$99.80
Sealant applicator handle	4	\$7.99	\$31.96	5	\$6.39
Mouth props	4	\$19.50	\$78.00	5	\$15.60
Patient mirrors (handheld)	2	\$8.99	\$17.98	5	\$3.60
Fans	2	\$15.00	\$30.00	5	\$6.00
Safety glasses	6	\$6.99	\$41.94	5	\$8.39
Storage unit for supplies	1	\$80.00	\$80.00	5	\$16.00
<b>Total Fixed Costs</b>			<b>\$86,356.75</b>		<b>\$19,990.61</b>

\*Life span determined by contacting manufacturer and determining the average lifespan of instruments/cavitron inserts used 2 to 4 times per week

Fee Lunch program, regardless of Medicaid coverage. The only form of reimbursement the program receives is from Medicaid claims for children with coverage. Of the 339 participating children, 144 (42.5%) had Medicaid coverage. The total amount of Medicaid reimbursement during the 2008 to 2009 term was \$1,618, representing 1.5% of the total costs (\$107,515.74) of operating the program.

### Comparison to Programs Staffed by Paid Dental Professionals

If a similar program staffed by paid dental professionals was to be developed, cost differences would primarily arise from 2 sources: salaries/wages and the time it takes to perform the procedures. To determine the costs associated with employing a paid ECP-I registered dental hygienist, the hourly salary listed on the Bureau of Labor Statistics website was utilized. For the state of Kansas, the mean hourly

salary for a registered dental hygienist is \$30.92.<sup>17</sup> Assuming that the registered dental hygienist works the standard 2,000 hours per year, the annual salary would be \$61,840, and the total benefits package would equal \$21,644, using the customary 35% rate.<sup>16</sup> This suggests that an additional \$10.82 should be added to the hourly wages to account for benefits as well, for a total of \$41.74.

Since the program does not operate 2,000 hours per year, the program manager's 1,456 hour contract plus additional time for administrative duties was used for this calculation. It was estimated that approximately 8 hours per week would be spent performing administrative tasks. Since the program provided services approximately 30 weeks during the 2008 to 2009 school year, an additional 240 hours were added to account for administrative duties. This suggests that \$70,791.04 (\$41.74 multiplied by 1,696 hours) should be allocated for

Table III: Standard Cost Profiles for Billable Procedures

Procedure	Cost	Items Included in Cost Calculation
Child Prophylaxis	\$9.85	Prophy Angle, Prophy Paste, 2x2 Gauze, Floss, Saliva Ejector, Patient Napkin, Infection Control Barrier Wraps, Sterilization Bags, Clinician Mask and Gloves, Toothbrush, Toothpaste, Floss, Disclosing Solution, Medicine Cups for Disclosing Solution
Two Bitewing Radiographs	\$0.41	Phosphor Plate Film Sleeves, Disposable Bitewing Tabs
Fluoride Varnish Treatment	\$1.56	Fluoride Varnish*
Sealants (per tooth)	\$2.87	Cotton Rolls/Dri-Angles, Sealant Material (single dose), Etchant Material (single dose)

\*All students received fluoride varnish at the time of Child Prophylaxis so no additional supplies were needed for the application

Table IV: Cost of Supplies Used in Multi-Procedure Encounters

Multi-Procedure Encounter Category	Cost Per Encounter	Quantity	2008 to 2009 Total Cost
Prophy + Bitewings + Fluoride Varnish + Sealants + Oral Hygiene Instruction	\$11.82(86)+2.87(246)	86	\$1722.54
Prophy + Bitewings + Fluoride Varnish + Oral Hygiene Instruction	\$11.82	171	\$2021.22
Prophy + Fluoride Varnish + Oral Hygiene Instruction	\$11.41	28	\$319.48
Prophy + Fluoride Varnish + Sealants + Oral Hygiene Instruction	\$11.41(4)+2.87(12)	4	\$80.08
Prophy + Bitewings + Oral Hygiene Instruction	\$10.26	2	\$20.52
Prophy + Oral Hygiene Instruction	\$9.85	3	\$29.55
Prophy + Bitewings + Fluoride Varnish	\$9.58	9	\$86.22
Prophy + Fluoride Varnish	\$9.17	1	\$9.17
Oral Hygiene Instruction Only	\$2.59	3	\$7.77
Total Costs of Disposable Supplies			\$4,296.55

n=number of sealants placed for all Multi-Procedure Encounters in that category

salary and benefits if a paid dental hygienist provided services for a program in operation the same amount of hours as Miles of Smiles. This figure is \$23,401.04 higher than the \$47,390.00 allocated for salary/benefits for the program manager and unpaid dental hygiene students (Table VI).

In addition, all ECP-I dental hygienists are required to carry a Professional Liability Insurance policy. Although a variety of liability insurance policies exist, the cost of the policy sponsored by the American Dental Hygienists' Association was used for the calculation. The annual policy is \$77; therefore, \$77 was added to the personnel costs for a program staffed by a paid dental hygienist (Table VI).<sup>18</sup>

When services were provided, the time required to complete them was documented in 15 minute increments. The average time spent per encoun-

ter was 3.18 units, or approximately 48 minutes. Although the literature does not provide a definite average time per encounter for registered dental hygienists, it can be assumed that a licensed professional with experience will likely perform procedures faster than a dental hygiene student that must have an instructor verify the accuracy of the treatment provided at many stages throughout the encounter. The American Dental Association's Survey of Dental Practice states that the number of patient visits per hour by pediatric dentists that employ part-time or full-time dental hygienists increases by 1 to 2 patients when including hygienist visits.<sup>19</sup> This suggests that the time per encounter by a dental hygienist likely ranges from 30 to 60 minutes. Since a dentist is not present to perform an exam (minimizing the amount of appointment time needed), an estimate of the amount of time it would take for a registered dental hygienist to perform preventive services is 30 minutes.

If a program was in operation 248.75 hours (14,925 minutes) per school year (the approximate amount of time the Miles of Smiles Program was in operation according to the time per encounter documented in the database), a dental hygienist could potentially have 497 patient encounters (14,925 minutes, 30 minutes per encounter) as compared to the 313 patient encounters of the Miles of Smiles Program. The price per encounter varies depending upon the procedures performed and supplies needed, but the average cost per encounter during the 2008 to 2009 school term was \$11.82. If a dental hygienist has 184 more encounters the cost of supplies will increase by approximately \$2,174.88 (Table VI).

On the other hand, increased numbers of patient encounters results in increased production. According to the database, the average production per encounter for the Miles of Smiles Program in 2008 to 2009 was \$81.93. This was calculated using Medicaid reimbursement rates for each procedure performed within the encounter. Whenever possible, a typical encounter included radiographs, prophylaxis, fluoride treatment, patient education and sealants. An additional 184 encounters could result in an approximate \$15,075.12 increase in production. Since the program's only form of reimbursement for services provided is through Medicaid, the additional production does not necessarily suggest additional reimbursement. Of the \$25,643 that was produced by the Miles of Smiles Program, only \$1,618 was reimbursed by the Kansas Medicaid Program. This equals approximately 6.3% of the total amount produced. It has been determined, however, that the program was not able to collect the entire amount of billable services for children with Medicaid coverage due to issues with transferring the data in a timely manner, therefore, that figure does not accurately represent the reimbursement potential. Since the data does not provide an accurate comparison of the expected reimbursement for additional production, no conclusions can be drawn based on the additional amounts of reimbursement expected. Assuming all other expenditures are the same, the cost of operating a similar program staffed by a licensed dental professional rather than supervised dental hygiene students is \$145,995.12, a total of \$38,479.38 more than the cost of the Miles of Smiles Program.

## Discussion

Although this study supports the contribution that the program has made in improving access to care for vulnerable populations, it also highlights the financial challenges in long-term sustainability of such a program.

Table V: Total Cost of Operating the Program During the 2008 to 2009 Term

Expenditure	Associated Cost
Fixed costs for equipment and instruments (Table II)	\$19,990.61
Variable costs – supplies utilized during patient encounters (Table IV)	\$4,296.55
Personnel expenditures	\$47,390.00
Total Direct Costs	\$71,677.16
Standard facilities and administration rate	
50% of total direct costs	\$35,838.58
Total Indirect Costs	\$35,838.58
Total Cost	\$107,515.74

Table VI: Comparison of Costs for Miles of Smiles to a Program Staffed by an Extended Care Permit Registered Dental Hygienist

Expenditure	Cost for Miles of Smiles	Cost for a School-Based Program Staffed by ECP Dental Hygienist
Fixed costs – equipment and instruments	\$19,990.61	\$19,990.61
Variable costs – supplies utilized during patient encounters	\$4,296.55	\$4,296.55 + \$2174.88 = \$6,471.43
Personnel expenditures	\$47,390.00	\$70,791.04 + \$77.00 = \$70,868.04
Total Direct Costs	\$71,677.16	\$97,330.08
Standard facilities and administration rate (50% of total direct costs)	\$35,838.58	\$48,665.04
Total Indirect Costs	\$35,838.58	\$48,665.04
Total Cost	\$107,515.74	\$145,995.12

## Sustainability

When reviewing the cost of operating the Miles of Smiles program, it is evident that the costs associated with operating the program far exceeded the

minimal amount of reimbursement received. Such a significant gap between the amount of reimbursement and cost highlights that funding from external sources is necessary for the program to continue long-term. It should be noted, however, that challenges associated with transferring data and billing contributed to the significant reimbursement gap. The program manager reports that during the first year of operation, the program was using a "store and forward" method of data collection and tracking as opposed to "real time" data collection, therefore, the data was often not transferred to the Patient Accounts office in a timely manner. According to an estimate, a total of \$17,104 could have been reimbursed for services provided to Medicaid eligible children, however, only \$1,618 was billed and collected due to aforementioned challenges. If the entire amount of \$17,104 was collected from Medicaid reimbursement, that figure would represent approximately 67% of the total production and approximately 16% of the overall costs of operating the program during the 2008 to 2009 school year. This figure is more closely aligned with Byck's findings discussed previously.<sup>5</sup> Recognizing this difference, the process has since been addressed and the program currently has a more effective method of transferring this data between the treatment site and the business office in "real time."

Despite these challenges, the potential amounts of reimbursement that could have been collected still suggest that the program does not generate enough revenue to sustain itself without external funding. Although grant funding was available initially to purchase a majority of the equipment and instruments and to help with personnel expenses, for the program to continue to operate in this capacity, securing additional and constant sources of external funding would be necessary. This is consistent with other school-based programs discussed in the literature that have been in operation for several years and rely on external funding from a variety of sources.<sup>11,12</sup>

If the program were to become self-sustainable, significant modifications to the design of the program would be necessary. In 2008 to 2009, the program recorded a total of 248.75 hours providing services. According to the Kansas Department of Education, all elementary schools within the school district must be "open for business" for 1,116 hours per year.<sup>20</sup> Therefore, services were provided during only 22% of the time that school was in session. It is possible that if the program were operating at a higher capacity, more reimbursement could be generated to help offset the expenditures. Furthermore, the possibility of adding a restorative component to the program could be explored. Adding this compo-

nent would not only allow the program to operate at a higher capacity, but could also result in higher amounts of reimbursement as restorative procedures are reimbursed at a higher rate.

### **Limitations**

The limitations of this study include the potential bias associated with performing the cost analysis on the program's first year of operation. Most new programs experience challenges in defining the procedures and policies associated with daily operation. As the program has continued to operate, these processes have been refined and contributed to the program running more efficiently. The program manager reported making changes to the enrollment processes to increase the number of students in the program. A higher volume of students suggests that the program has become more efficient in providing treatment and generating patient encounters to verify that all the children enrolled in the program receive treatment.

Several assumptions were made in making the comparisons between the Miles of Smiles Program and a similar program staffed by a dental professional, as there is no published literature related to the average amount of time dental hygienists spend providing preventive services for children. It was assumed that a program staffed by paid dental hygienists would use identical equipment and amounts of supplies and that all patient encounters would take an average of 30 minutes. Despite the assumptions, the results do provide an estimated cost prediction for professionals that are interested in implementing a school-based program.

### **Directions for Future Research**

This study lends itself to several opportunities for future research. Now that the Miles of Smiles program has been in operation for several years, the processes have been refined and resulted in increased productivity and an improved system for filing insurance reimbursement claims. An updated, identical cost analysis of the Miles of Smiles Program would allow for valuable comparisons of productivity as the program has evolved. This would eliminate any bias associated with analyzing the program's first year of existence.

Since the Miles of Smiles Program operated only 22% of the time that school was in session during 2008 to 2009, it is worth exploring the change in costs if the program were operating at various increased capacities and its effect on the program's sustainability. Operating at a higher capacity will result in an increase in variable costs and personnel

expenses so the impact that a change in program design would have is unclear.

It is recommended that further research take place to compare the cost-analysis to a school-based preventive oral health program already established that utilizes paid dental professionals. As stated previously, several assumptions were made when answering Research Question #3, so having exact data related to the time allotted per procedure, the supplies used and administrative duties would provide a more precise comparison to the Miles of Smiles program. In addition, some existing school-based programs provide both preventive and restorative treatment by employing a dentist and a dental hygienist. Making comparisons between the costs associated with these programs and reimbursement rates to that of a preventive program only could provide support in determining if the program can minimize costs and increase reimbursement rates if restorative procedures are provided as well.

## Conclusion

Within the limitations of this analysis, the following conclusions can be drawn:

- The cost of operating the Miles of Smiles Program in 2008 to 2009 was \$107,515.74.
- The amount of Medicaid reimbursement for services provided in 2008 to 2009 was \$1,618.00. This represents 6.3% of the total amount produced and 1.5% of the program's total annual operating cost. A total of \$17,104 could have been reimbursed for services provided to Medicaid-eligible children, but challenges associated with data transfer and billing procedures resulted in a much lower reimbursement rate. These challenges have been addressed and the

data is being transferred in "real time" to facilitate billing. The data suggests that even if the entire \$17,104 would have been collected, the program is not self-sustainable and additional sources of funding for long-term operation need to be secured.

- If a similar program staffed by dental professionals was implemented, the program would cost approximately \$38,479.38 per year more. This increase is attributed to higher salaries/wages, more supplies used, and the costs associated with administrative duties. Although more reimbursement is predicted, it will not offset the additional costs.
- There have been several lessons learned for the Miles of Program since its first year of operation in 2008 to 2009. Since the program has had time to refine the processes and procedures, it is likely that some of this data may vary if a current analysis was performed on the program.

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## References

1. The dental access gap – findings from a national survey. Lake Research Partners [Internet]. 2011 [cited 2011 October 30]. Available from: [www.wkkf.org/.../00E17806D74E45D6BE6A6FE8ECA1A89A.ashx](http://www.wkkf.org/.../00E17806D74E45D6BE6A6FE8ECA1A89A.ashx)
2. Mouradian WE, Wehr E, Crall JJ. Disparities in children's oral health and access to dental care. *JAMA*. 2000;284(20):2625-2631.
3. Improving access to oral health care for vulnerable and underserved populations. Institute of Medicine of the National Academies [Internet]. 2011 July 13. Available from: <http://www.iom.edu/Reports/2011/Improving-Access-to-Oral-Health-Care-for-Vulnerable-and-Underserved-Populations.aspx>
4. Dankwa-Mullan I, Rhee KB, Williams K, et al. The science of eliminating health disparities: Summary and analysis of the NIH summit recommendations. *Am J Public Health*. 2010;100:(Suppl 1) S12-S18.
5. Byck GA, Cooksey JA, Russinof H. Safety-net dental clinics. *J Am Dent Assoc*. 2005;136(7):1013-1021.
6. Milgrom P, Mancl L, King B, Weinstein P, Wells N, Jeffcott E. An explanatory model of the dental care utilization of low-income children. *Med Care*. 1998;36(4):554-566.
7. The U.S. oral health workforce in the coming decade. Institute of Medicine of the National Academies [Internet]. 2009 [cited 2009 December 28] Available from: [www.iom.edu/Reports/2009/OralHealthWorkforce.aspx](http://www.iom.edu/Reports/2009/OralHealthWorkforce.aspx)
8. Guo JJ, Wade TJ, Pan W, Keller K. School-based health centers: Cost-benefit analysis and impact on health care disparities. *Am J Public Health*. 2010;100(9):1617-1623.
9. Albert DA, McManus JM, Mitchell DA. Models for delivering school-based dental care. *J Sch Health*. 2005;75(5):157-161.
10. Niederman R, Gould E, Soncini J, Tavares M, Osborn V, Goodson JM. A model for extending the reach of the traditional dental practice: The ForsythKids program. *J Am Dent Assoc*. 2008;139(8):1040-1050.
11. ForsythKids. The Forsyth Institute [Internet]. [cited 2011 October 30]. Available from: <http://www.forsyth.org/kids/index.html>
12. Mobile Services. Apple Tree Dental [Internet]. [cited 2011 October 30]. Available from: [http://www.appletreedental.org/dental\\_care/mobile\\_dental\\_care](http://www.appletreedental.org/dental_care/mobile_dental_care)
13. Kansas dental practices act statues and regulations and related law relating to dentists and dental hygienists. Kansas Dental Board [Internet]. 2010 [cited 2011 October 20]. Available from: [http://www.kansas.gov/kdb/Documents/Dental%20practicesactregsandrelatedlaws406\\_files/DENTALPRACTICESACTNOVEMBER2010.pdf](http://www.kansas.gov/kdb/Documents/Dental%20practicesactregsandrelatedlaws406_files/DENTALPRACTICESACTNOVEMBER2010.pdf)
14. Simmer-Beck M, Gadbury-Amyot CC, Ferris H, et al. Extending oral health care services to underserved children through a school-based collaboration: Part 1: A descriptive overview. *J Dent Hyg*. 2011;85(3):181-192.
15. Keselyak NT, Simmer-Beck M, Gadbury-Amyot CC. Extending oral health care services to underserved children through a school-based collaboration: Part 2 – The student experience. *J Dent Hyg*. 2011;85(3):193-203.
16. University of Missouri-Kansas City Office of Research Services. Calculate F&A Costs. University of Missouri-Kansas City [Internet]. [cited 2010 June 12]. Available from: <http://ors.umkc.edu/pre-award/proposals-and-grants/budgets/fa-costs>
17. Occupational Employment and Wages-May 2011 Dental Hygienists. Bureau of Labor Statistics [Internet]. 2011 [cited 2011 October 20]. Available from: <http://www.bls.gov/oes/current/oes292021.htm>
18. Dental Hygiene-Focus on Advancing the Profession. American Dental Hygienists' Association [Internet]. [cited 2011 Octobr 30]. Available from: [www.adha.org/downloads/ADHA\\_Focus\\_Report.pdf](http://www.adha.org/downloads/ADHA_Focus_Report.pdf)
19. Survey of Dental Practice 2010. American Dental Association [Internet]. [cited 2011 November 2]. Available from: <http://www.ada.org/1619.aspx>
20. 1,116 Hour Calendar. Kansas State Department of Education [Internet]. [cited 2011 November 2]. Available from: <http://www.ksde.org/LinkClick.aspx?fileticket=MCoQwnj7SMs%3D&tabid=1877&>

## Public Health Dental Hygiene: An Option for Improved Quality of Care and Quality of Life

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### Introduction

Lack of access to oral health care education, preventive and treatment services continues to plague un-served and underserved children, families and elderly in Wisconsin.<sup>1</sup> The Northern Area Health Education Center (NAHEC) provides services covering multiple counties in the upper one third of the state in an attempt to improve access to health care to underserved communities. One way NAHEC meets these goals is through educating current and future health care professionals. Another is supporting preventive public health outreach programs. NAHEC serves a 33 county, 30,443 square-mile area, larger than Massachusetts, New Hampshire, Vermont and Delaware combined.<sup>1</sup> Forty-six percent of the state's land mass and 22% of its population, equating to approximately 1.1 million persons, are encompassed here.<sup>1</sup>

### Health Professional Shortage Areas

The Health Resources and Services Administration maintain lists of designated Primary Medical Care, Mental Health and Dental Health Professional Shortage Areas, called HPSAs.<sup>2</sup> Geographic areas are designated as Health Professional Shortage Areas (HPSA) based on the following criteria:<sup>2</sup>

- The area has a population to full-time equivalent primary care physician ratio of at least 3,500:1
- The area has a population to full-time equivalent primary care physician ratio of less than 3,500:1 but greater than 3,000:1 and unusually high needs for primary care services or insufficient capacity of existing primary care providers
- Primary medical care professionals in contiguous areas are over utilized, excessively distant or inaccessible to the population of the area under consideration

### Abstract

**Purpose:** The purpose of this research was to document quality of life (QoL) and quality of care (QoC) measures for families receiving care from dental hygienists within public health departments, and to consider if oral health for families with economic disparities and cultural differences was improved.

**Methods:** A descriptive research study using a retrospective record review was conducted considering QoC. A review of state epid "Do preventive oral health programs based in local health departments provide quality care services, thus impacting QoL for underserved populations?"

**Results:** A dental hygienist working in public health made significant contributions to improving access to care and QoL in a rural, socio-economically disadvantaged community. A total of 2,364 children received education, 1,745 received oral screenings and 1,511 received dental sealants. Of these, 804 children with caries were referred, with 463 receiving restorations and follow-up care. QoL metrics basis assessed Health Outcomes & Health Determinants. Initial QoL data was ranked in the bottom half of the state, while 70% of original determinant data was also ranked in the bottom half of reported metrics.

**Conclusion:** Dental hygienists in public health settings can positively affect patients offering preventive care outreach services. Education and sealant placement were considered effective as measured by access, delivery and, when required, referral for restorative care. Improvement in QoL for individuals was noted through improved health outcomes and determinant metrics.

**Keywords:** quality of life, quality of care, outcomes, health disparities, prevention, education, allied health, dental hygiene, access to care, workforce development

This study supports the NDHRA priority area, **Health Services Research:** Investigate how alternative models of dental hygiene care delivery can reduce health care inequities.

Many Northern Wisconsin communities are rural and underserved as defined by national health care standards.<sup>2</sup> Thirty of the 64 federally designated Primary Medical Care HPSAs occupy the Northern region (47%), and 26 of the state's 43 federally designated Dental HPSAs are also in the same region (60%).<sup>1</sup> Five of the 11 counties described in the service area are Dental HPSAs.<sup>1-2</sup> The combined populations of these counties exceed the state average of persons aged 65+ by more than 5%. The percentage of persons living below poverty levels also exceeds state averages.<sup>1</sup>



This geographic area is also home to 5 Native American Sovereign Nations. Accessing dental care services for Native Americans depends on varying tribal standards, restrictions and clinic location. Only 1 tribal clinic exists in the geographic service area described. Individuals from other minority groups, or those socioeconomically disadvantaged, cannot typically access dental care services through the tribal clinic.

## **Problem**

Little research exists describing both Quality of Life (QoL) and Quality of Care (QoC) for individuals accessing dental services.<sup>3-4</sup> No research exists describing QoL and QoC for individuals accessing preventive dental care services offered by dental hygienists through public health departments. Dental hygienists in local communities are working through the public health department providing oral health education, preliminary screenings and preventive care services. Once individuals are screened, and preventive health care services provided, public health dental hygienists follow a consultation and referral model for addressing restorative care needs. Following systems protocols, referrals are made to Federally Qualified Health Clinics and Community Health Centers and/or private dentists for restorative dental services and case management.<sup>2</sup>

## **National Oral Health Care Disparities and Issues**

A number of reports confirm the existence of health care disparities nationally.<sup>5-29</sup> Of special significance are the reports relating to oral care, including Oral Health in America: A Report of the Surgeon General, and the National Call to Action promoting Oral Health.<sup>5,6</sup> Low income and minority populations often lack access to oral health care, causing significant health care disparities. If the ultimate goal of oral health care is disease prevention, focusing on providing care to children seems the most focused approach to achieving success. Once oral health education and preventive care services are provided, it is further necessary to assure individuals experiencing disease are treated efficiently and effectively. An inadequate number of providers is one barrier to offering restorative care, while demographic location and socioeconomic disparities are additional barriers. With inadequate numbers of dentists in the workforce, restorative and surgical needs remain unmet.<sup>7</sup> Dentist/population ratios stand at 58/100,000, however, this proportion is projected to decline to 45/100,000 by 2020.<sup>7-8</sup> One solution to declining numbers of restorative care providers includes expanding the dental hygiene scope of practice, addressing workforce inadequacies.<sup>10-18</sup>

Populations and groups present with unique and varying care and access needs. Barriers need to be

removed so all people can access preventive and restorative care. Regardless of the needs and differences of populations being studied, be they children, migrant workers, indigenous populations, or those with socioeconomic or demographic differences, no one solution to accessing services is perfect for any specific group.<sup>18-29</sup> Even for those with adequate financial resources, access to care still provides barriers.<sup>10</sup> Current literature does not describe care or resultant impacts on QoC and QoL for patients accessing care through public health departments.

## **Care Models for Education and Provision in Other Locations**

Different models for bridging the access to care gap and addressing workforce development are necessary. The Advanced Dental Hygiene Practitioner, Dental Health Therapist and Public Health Dental Hygiene Practitioner models can assist in developing and expanding the workforce for meeting oral care needs.<sup>9-13,15-18,30-32</sup> Expanding the scope of dental practice and numbers of advanced educational programs available providing education and training for mid-level providers can aid in overcoming workforce development and access to care barriers. The dental therapist model is recognized internationally as an approach for improving access, while reducing care disparities cost efficiently.<sup>30-33</sup> Educational curriculum programs combining preventive, restorative, surgical and periodontal content can provide for care needs of both children and adults.<sup>10</sup>

## **State Health Care Disparities, Access and Demographic Issues**

National disparities are mirrored within the state.<sup>9-10,30-39</sup> Inadequate workforce numbers for meeting oral health care restorative needs exist.<sup>37-39</sup> Problems associated with access to care are compounded by not only provider numbers, but demographic distribution, ethnicity, practice background/orientation and education.<sup>9-10,30-39</sup> Demographic issues alone provide significant challenges to accessing care.<sup>9-10,30-38</sup> Data is collected annually by the States' Population Health Institute documents Programs and Policies, Health Factors and Health Outcomes by county.<sup>40</sup> Health Factors data documents clinical care provision, including access and QoC, while Health Outcomes document morbidity as one measure of QoL.<sup>40</sup>

## **Quality of Life**

QoL is defined as the general well being of individuals and societies, based on wealth, employment, environment, physical and mental health, education, recreation and leisure time, and a sense of social belonging.<sup>39,41</sup> Dental disease, along with these fac-

tors, affects QoL.<sup>39,41-48</sup> The Population Health Institute ranks QoL annually for each of the states' 72 counties. Rankings are based on weighted summaries for individual communities that consider quality of health care, environment, individual behaviors, education and jobs.<sup>49</sup> Ranking is dynamic, based on changes as counties improve health outcomes by addressing all health factors with effective, evidence based programming and policies.<sup>49</sup> Adequately measuring and documenting QoL outcomes has been considered elusive by researchers and experts, as epidemiologic data being collected and evaluated is renormed annually. Norm, rather than criterion referencing for this measure, is a significant issue while considering the validity of findings. County and state rankings are triangulated with data from the Centers for Disease Control (CDC).<sup>49</sup> Results are considered both a call to action and used as necessary data tools for evidence based decision making for change initiated by community leaders.

### **Quality of Care**

The 21st Century Institute of Medicine definition of QoC includes care that is safe, effective, patient centered, timely, efficient and equitable.<sup>46</sup> Thus, safety is the foundation upon which all other aspects of quality care are built. The Population Health Institute considers clinical care as a measure of health factors combining both access and quality of care.<sup>49</sup> Health behaviors, local environment and social and economic factors are also evidence-based measures considered annually. Clinical care accounts for 20% of this measure, health behaviors account for 30%, social and economic factors 40% and environmental factors 10%. Even though clinical care accounts for only 20% of this measure, both access to and QoC impact county performance rankings. This data is used for public health policy formation and implementation within public health departments.<sup>49</sup>

### **Protocols for Care in Service County**

Service and care protocols for meeting the challenges of improving both QoL and QoC measures in the demographic region are documented and followed.<sup>50</sup> Evidence based practice drives clinical care provision, providing care for populations with low socioeconomic status and/or diverse ethnic backgrounds.

### **Purpose**

The purpose of this research was documenting QoL and QoC measures for families receiving care from dental hygienists within public health departments, and considering if oral health for families with economic disparities and cultural differences improved.

## **Methods and Materials**

A descriptive research study was conducted following Institutional Review Board approval and exemption. Using a retrospective records review, public health data from 2004 through 2009 was examined. The research question the study sought to address was: "Do preventive oral health programs based in local health departments provide QoC Services, thus impacting QoL for underserved populations in Dental HPSAs?" Records evaluated describe documenting access to select oral health care services and the resultant outcomes for individuals living in rural, socioeconomically disadvantaged communities.

### **Population and Sample**

The study sample was drawn from a rural population within 1 of the state's 72 counties in a geographically isolated region in the northern third of the state. One county's records were examined. The study's convenience sample included 2,364 CDC Sealant Efficiency Assessment for Locals and States (CDC SEALS) records spanning a 6 year period. These records held data for all children accessing various oral health care services through a county's public health school based outreach program. A limitation of this approach is generalizability of findings to larger populations. The demographic breakdown of the study population is in Table I.

### **Data Collection & Analysis**

Data analysis was descriptive in nature, documenting and evaluating existing data from the CDC SEALS records for clients served in the county studied. This information begins documenting access to oral health care services offered by dental hygienists working through public health departments in rural, socioeconomically disadvantaged communities. Data from the CDC SEALS database for preventive care services documents various QoC measures. Data from the University of Wisconsin School of Medicine and Public Health Reports was examined for documenting QoL measures.<sup>49</sup> For the purposes of this study, data analysis for quality of care measures specifically focused on care provided to children through the school-based sealant program.

## **Results**

### **Quality of Care**

A review of CDC data indicated 2,364 children received oral health education (100%), of which 1,745 (74%) of the children educated received oral screenings. Cumulative and annual results are documented in Table II. Of the 1,745 children screened, 1,511 (87%) had dental sealants placed, and 804 (46%) with dental caries were referred to federally qualified

Table I: Demographic Summary

Year	2004	2005	2006	2007	2008	2009	Total
White	306	267	255	210	223	191	1452
Black	0	4	0	0	4	2	10
Asian	0	0	0	0	0	0	0
Hispanic	0	5	1	0	2	2	10
Native American	6	6	2	3	6	2	25
Pacific Islander	1	3	1	1	1	1	8
Other	1	1	0	2	0	0	4
Non-Reporting	0	0	0	0	0	2	2
Female	4	10	2	4	7	5	32
Male	4	9	2	2	6	4	27
Cumulative							
Minority Groups	8	19	4	6	13	9	59

Table II: Cumulative and Annual Analysis of School Based Sealant Program Results

Year	Number of Children Educated	Children Screened	Untreated Decay	Need for Urgent Care	Need for Early Care	Children Given Sealants in Program	Referrals Made
2004	484	380	113	6	104	314	153
2005	595	348	173	4	77	286	83
2006	379	281	159	15	54	259	68
2007	315	240	114	8	56	216	65
2008	328	263	138	14	42	236	57
2009	263	233	107	2	36	200	37
Total	2364	1745	804	49	369	1511	463

health centers or private practices for restorative services. Of the 804 children referred, 463 (58%) had dental restorations placed and received follow-up care. Referrals follow a consultative referral protocol.<sup>50</sup> Fifty-nine minority children (3.9%) received services and the populations and care provided are described in Tables I and II. Additional analyses revealed 30 to 35% of the total counties' school-aged child population were Medicaid recipients. Twenty percent of those accessing services had private dental insurance and self-selected out of the program, while the remaining children (45%) receiving care were uninsured.

### Quality of Life

The UW School of Medicine and Public Health yearly reports, the Wisconsin County Health Rankings, noted Northern Highland counties were almost all rated below state averages.<sup>49</sup> Health rankings are 1 to 72, 1 being best and 72 worst, based on the number of counties in the state. Of special note, under the category Health Outcomes (based on excess deaths and self-reported health status), 80% of Northern High-

land counties metrics consistently ranked in the bottom half of the state (Table III). While considering another key measure, Health Determinants (reflecting health care, health behaviors, socioeconomic factors and physical environment), 70% of Northern Highland counties also ranked in the bottom half of the state.<sup>49</sup> Examination of the QoL metrics indicate significant needs for the persons living in these rural areas. It is notable that QoL rankings from 2004 to 2011 show only gradual improvements.

### Discussion

Study findings provided illustrate similar national findings. The PEW Report provided Wisconsin with a grade of "C," identifying the states meeting 4 of 8 benchmarks.<sup>14</sup> Similar problems plaguing national populations- lack of access to oral care and being socioeconomically disadvantaged also plague the population described in this study.<sup>5-6,11-29</sup> A childhood of dental issues can lead to a lifetime of oral health problems, if early interventions are not implemented. Relatively low cost solutions including oral health

education, fluoride and sealant programs can result in less time lost at school, work, less disease burden and less pain. Long-term impacts from dental disease burden on the entire health care system population could be reduced with education, early intervention and changes in workforce paradigms.

Table I describes the demographics of the population served in Wisconsin. Of the 1,511 children receiving services, it should be noted only 59 (3.9%) were from reported minority groups. A total of 1,452 (96.1%) children receiving service were Caucasian. The largest of the minority groups receiving sealants as a preventive care measure were Native American (25, 1.6%). Where the overarching program goal was improving oral health for families with economic disparities and cultural differences, the data documents the cultural groups reported here were an extremely small percentage of those actually served.

Additional analysis of socioeconomic status determined 30 to 35% of the study populations were Medicaid recipients, and approximately 45% were uninsured. These findings illustrate the socioeconomic need and status of children and families accessing care through the school based sealant program. Dental hygienists offering low cost, education and prevention programs through public health departments can positively impact the health of individuals within communities when services are offered through local area schools.

While considering data in Table II regarding QoC, it should be noted the initial numbers of children screened and treated were higher, declining over time. The reasons for this were two-fold: first, funding supporting the programs became restricted, and secondly, there were changes in the numbers of schools participating in the program. Direct connections between program participation and school funding reductions were identified. As school budgets declined preventive programs, similar to the Arts, were some of the first cancelled. Numbers of children screened also declined. This decline was directly proportional to reduced funding, and school district boards determining they could no longer participate in preventive health programs, even though these programs were clearly cost efficient in relation to preventing community disease burden. Individuals on educational boards often do not understand how disease affects student performance, resulting in lost productivity or classroom hours when making budgetary cuts. From a public health perspective, funding these programs for community vitality is wise. Data in Table II also documented declines over time in numbers of children requiring urgent care as they entered the referral pipeline for restorative care. Children requiring early care also declined over time as referrals were made

Table III: Cumulative Description of County Health Rank

Year	Descriptor	n
2004	QoL ranking	55/72
2005	QoL ranking	51/72
2006	QoL ranking	66/72
2007	QoL ranking	66/72
2008	QoL ranking	58/72
2009	QoL ranking	Data unavailable
2010*	QoL ranking	61/72
2011*	QoL ranking	53/72

through the preventive program for required intervention and treatment. Declining disease burden in the communities' children resulted in declining need for restorative care. Numbers of children participating in and receiving oral health education and dental sealants in the program remained constant from year to year, possibly as a result of families recognizing using preventive measures resulted in lowering care expenses and oral disease burden. Numbers of referrals required for restorative care also declined over time. The consultative/referral model works successfully for meeting the preventive and restorative care needs of children in this community in a cost efficient manner. Implementing various school based outreach programs through public health departments can expand access to care for minority and socioeconomically disadvantaged, underserved populations across the country. Implementation of educational and preventive programs like these also allows dental hygienists to pursue alternative career options beyond traditional clinical practice. Dental hygienists employed through public health departments can make significant contributions improving both access to and quality of care for school-aged children.

Consideration of the data reflecting QoL measures and findings is slightly more problematic as reported in Table III. The University of Wisconsin Population Health Institute has produced the Wisconsin County Health Rankings as part of epidemiologic data tracked by the University of Wisconsin School of Medicine and Public Health.<sup>41</sup> Data appears to document improvements, however slight, in the epidemiologic reporting on the QoL measures for the population studied. QoL metrics basis were 2 categories: Health Outcomes (deaths/self-reporting health status) and Health Determinants. Determinant data included health behaviors, socioeconomic factors and physical environment. Initial QoL outcomes data for 80% of recipients ranked in the bottom half of state, while 70% of person's original determinant data was also ranked in the bottom half of reported metrics. Counties were ranked from 1 to 72, 1 being considered the best county to live in

and 72 the worst. Each year, for both categories, the public health department studied has made improvements as reflected in the QoL data. Where cumulatively the county still ranks in the lower third for this overall measure, it appears yearly rankings are slowly improving.<sup>49</sup> Significant concerns exist with using this data for determining if QoL was truly improved for the population studied. First, data is reformed annually. Thus, data is dynamic in nature. Secondly, data gathered and analyzed for this measure continues evolving as public health concerns evolve. With data being reformed annually, and resultant changes from said re-norming, data validity becomes questionable. Another consideration includes inter-examiner consistency and reliability for those gathering and reporting data with epidemiologic research team changes. When measuring QoL, these are significant limitations affecting consistency of the state's epidemiological data. If differing researchers are considering and reporting on the analytic data found, yearly differences in interpretation or results are likely being reported. Politicians and public policy makers use these health data outcomes for determining funding of public health programs. This raises troubling questions about social justice when state funding supporting public health preventive care programs is limited when data for determining state health outcomes lacks consistency from year to year.

Identifying QoL metrics might be better measured using a survey. Surveying populations receiving care might be a better technique for gathering data determining if quality of life has been improved. An appropriate survey focused on QoL questions would need to be developed. A survey might provide better insight into people's perception of improved QoL rather than reliance on broader, epidemiologic data for making that determination. One recommendation for a future study includes conducting a focused survey asking questions determining if QoL was impacted rather than using state and national data from an epidemiologic perspective.<sup>49</sup> Additional study determining QoC and QoL for other public health departments programs in the Dental HPSA shortage areas should be conducted. A final recommendation includes further developing and offering a conceptual framework considering the intersections between QoC, QoL, workforce development and access to care issues. This conceptual model could be used as a benchmark tool using QoC and QoL for measuring impact of public health dental hygiene practice and program effectiveness.

Two apparent issues emerged from this investigation: significant access and demographic bottlenecks exist in the pipeline to oral health care services and workforce development issues as noted by a documentable lack of providers. Both these issues have multifactorial considerations, and each is considered separately.

## **Access to Care**

Considerable effort has been undertaken highlighting access to care issues. Recent reports developed by Beazoglou et al<sup>51</sup> and Bailit<sup>52</sup> for the state's dental association and department of health services workforce development taskforce took the perspective that Wisconsin's dental workforce needs are no more than a marketing supply and demand issue, rather than access to care issue. The predominant issues are deeper than marketing, and several issues regarding access to care require consideration.<sup>51-55</sup> Several potential solutions are offered here for discussion.

## **Number of Work Hours per Calendar Year**

The average person working full time spends approximately 1,750 to 2,000 hours each year at work.<sup>56,57</sup> Beazoglous' Wisconsin dental workforce study reported practices averaging 1,385 hours per year.<sup>51</sup> Analysis of this data identified dental care providers worked 415 to 615 hours less than full time employees in various businesses and industry.<sup>53-57</sup> According to Beazoglous' convenience survey, it was reported restorative services were offered 30 to 32 hours per week.<sup>51</sup> This equates to 43 weeks of part time work, with 5 weeks unscheduled yearly.<sup>51,53,54,56,57</sup>

Access to restorative care services illustrated by this data alone highlights one access to care issue. If oral care practitioners worked the same amount of time as other health care providers or full time employees in business and industry, access issues might decline. Dental hygienists performing expanded functions could have foreseeable impact on QoL for residents located in rural, socioeconomically disadvantaged communities. Broadening access to care, while increasing workforce capacity and improving QoL could be achieved using the Advanced Dental Hygiene Practitioner, Dental Health Therapist or Public Health Dental Hygiene Practitioner models for meeting oral care needs.<sup>11-13,15,16,30,31</sup>

## **Scheduling Practices**

Scheduling practices typically follow traditional business models. Scheduling presents another access to care issue. Access to oral health care services, similar to medical care, should follow Medical Models.<sup>32,58-61</sup> Dental hygienists working through public health departments can expand access by offering care in alternative settings, at alternative times, for meeting care needs of community populations.

## **Care Models**

Another actionable consideration for improving access to care includes developing and putting in place

Clinical Emergency Models. In the Medical Model, people access the Emergency Room for acute care and services.<sup>32,33,58-61</sup> Similar to the Medical Model, “safety net” dental clinical locations could provide dental emergency care. Once emergency care is provided, patients are referred back to community practices. In this way, there are clearly defined “safety nets” for care reducing barriers to access.<sup>13,58-61</sup> Dental hygienists trained in providing expanded functions, can similarly affect access to care.

### Removal of Practice Restrictions

Another bottleneck exists at the system level - legislative restrictions regarding access to care currently exists.<sup>62,63</sup> Dental hygienists occupational preparation includes providing educational and preventive care services for individuals, groups and communities.<sup>15,16</sup> Hygienists are being limited by legislative practice acts to providing care within specific practice settings or locations. Changing legislative codes would allow dental hygienists to provide their full scope of practice if legislative practice act restrictions are removed.<sup>62,63</sup>

Measureable actions like these can begin shifting oral health care disparities. For changes to occur legislators and restorative oral health care providers mental paradigms have to shift first. Access to care ultimately improves QoC and QoL for all citizens. Increasing the number of provider service hours worked, modifying scheduling practices, and developing emergency care locations are practical and viable solutions to addressing access concerns. Removal of legislative restrictions is another solution for addressing problems associated with accessing care.

### Workforce Development

Workforce development is another opportunity. Declining numbers of restorative practitioners due to impending retirements, stagnant workforce develop-

ment and state demographic issues are important considerations associated with accessing care, even if unpublished state data minimizes these problems.<sup>51,52</sup> Career laddering and educational opportunities for dental hygienists offering expanded functions can assist in developing and expanding the workforce for meeting oral care needs of the populace.<sup>11,15,58-61,64</sup> Using alternative care models and hygienists trained in expanded function care services can impact QoC and QoL for patients in underserved, socioeconomically disadvantaged rural communities.

### Conclusion

Dental hygienists delivering services through public health departments can influence QoL through QoC services. As a result of this descriptive research, oral health education and sealant delivery were deemed safe through Wisconsin Dental Examining Board records and clinically effective (SEALS database). It was determined the consultation and referral model works effectively for linking individuals with restorative services, including routine follow up. Additionally, alternative programs can improve access to care for individuals with economic disparities and cultural differences.

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## References

1. About Us. Wisconsin Area Health Education Centers [Internet]. [cited 2010 Nov 1]. Available from: <http://www.ahec.wisc.edu/>
2. U.S. Department of Health and Human Services. HRSA Designation Criteria. U.S. Department of Health and Human Services. 2010.
3. McGrath C, Bedi R. The value and use of 'quality of life' measures in the primary dental care setting. *Prim Dent Care*. 1999;6(2):53-57.
4. Astrom A, Ekback G, Ordell S, Unell L. Social inequality in oral health related quality-of-life, OHQoL, at early older age. *Acta Odontol Scand*. 2011;69(6):334-342.
5. U.S. Department of Health and Human Services. Oral Health in America: a report of the surgeon general. U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health. 2000.
6. U.S. Department of Health and Human Services. National call to action to promote oral health: A public-private partnership under the leadership of the office of the surgeon general. U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health. 2003.
7. Dentists: Occupational Outlook Handbook. Bureau of Labor Statistics [Internet]. 2008. Available from: <http://www.bls.gov/oco/ocos072.htm>
8. Healthiest Wisconsin 2020: Everyone living better longer. Wisconsin Department of Health Services [Internet]. 2010 [cited 2011 April 16]. Available from: <http://dhs.wisconsin.gov/statehealthplan/hw2020/index.htm>
9. Direct Access States. American Dental Hygiene Association [Internet]. 2009 [cited 2011 April 16]. Available from: <http://www.adha.org/direct-access>
10. Access for all: strategies for increasing access to primary health care. Wisconsin Primary Health Care Association [Internet]. 2009 [cited 2011 April 16]. Available from: <http://www.wphca.org>
11. Nash DA, Friedman JW, Kardos TB, et al. Dental therapists: a global perspective. *Int Dent J*. 2008;58(2):61-70.
12. Nash DA. Expanding dental hygiene to include dental therapy: improving access to care for children. *J Dent Hyg*. 2009;83(1):36-44
13. Niederman R, Gould E, Soncini J, Tavares M, Osborn V, Goodson JM. A model for extending the reach of the traditional dental practice: the ForsythKids program. *J Am Dent Assoc*. 2008;139(8):1040-1050.
14. The cost of delay: state dental policies fail one in five children. Pew Center on the States [Internet]. 2010. Available from: [http://www.pewtrusts.org/uploadedFiles/Cost\\_of\\_Delay\\_web.pdf](http://www.pewtrusts.org/uploadedFiles/Cost_of_Delay_web.pdf)
15. Lyle DM, Malvitz DM, Nathe C. Processes and perspectives: the work of ADHA's task force on the Advance Dental Hygiene Practitioner (ADHP). *J Dent Hyg*. 2009;83(1):45-47.
16. Competencies for the Advanced Dental Hygiene Practitioner (ADHP). American Dental Hygienists' Association [Internet]. [cited 2011 Mar 10]. Available from: <http://www.adha.org/downloads/competencies.pdf>
17. Hyde, Satariano S, WA, Weintraub, JA. Welfare dental intervention improves employment and quality of life. *J Dent Res*. 2006;85(1):79-84.
18. Manski MC, Parker ME. Early childhood caries: knowledge, attitudes, and practice behaviors of Maryland dental hygienists. *J Dent Hyg*. 2010;84(4):190-195.
19. Lukes SM. Oral health knowledge attitudes and behaviors of migrant preschooler parents. *J Dent Hyg*. 2010;84(2):87-93
20. Quandt SA, Clark HM, Rao P, Arcury TA. Oral health of children and adults in Latino migrant and seasonal farm worker families. *J Immigr Minor Health*. 2007;9(3):229-235.
21. Slesinger DP. Health status and needs of migrant farm workers in the United States: a literature review. *J Rural Health*. 1992;8(3):227-234.
22. Hansen E, Donohoe M. Health issues of migrant and seasonal farmworkers. *J Health Care Poor Underserved*. 2003;14(2):153-164.
23. Lukes SM, Miller FY. Oral health issues among migrant farm workers. *J Dent Hyg*. 2002;76(2):134-140.

24. Wells PL, Caplan DJ, Strauss RP, Bell D, George M. An oral health survey of the Lumbee Tribe in southeastern California. *J Dent Hyg.* 2010;84(3):137-144.
25. Jones DB, Niendorff WJ, Broderick EB. A review of the oral health of American Indian and Alaska native elders. *J Public Health Dent.* 2000;60(Suppl 1):256-260.
26. Broderick EB, Niendorff WJ. Estimating dental treatment needs among American Indians and Alaska natives. *J Public Health Dent.* 2000;60(Suppl 1):250-255.
27. Jansson H, Lindholm E, Lindh C, Groop L, Bratthall G. Type 2 diabetes and risk for periodontal disease: A role for dental health awareness. *J Clin Periodontol.* 2006;33(6):408-414.
28. Schroth RJ, Harrison RL, Moffatt ME. Oral health of indigenous children and the influence of early childhood caries on childhood health and well-being. *Pediatr Clin North Am.* 2009;56(6):1481-1499.
29. Maupomé G, Karanja N, Ritenbaugh C, Lutz T, Aickin M, Becker T. Dental caries in American Indian toddlers after a community-based beverage intervention. *Ethn Dis.* 2010;20(4):444-450.
30. Dyer TA, Robinson PG. Public awareness and social acceptability of dental therapists. *Int J Dent Hyg.* 2009;7(2):108-114.
31. Finkelman R. The public health dental hygiene practitioner: an alternative perspective. *Access.* 2009;23(7):26-29.
32. Janus K, Amelung V, Baker L, Gaitanides M, Schwartz F, Randall T. Job satisfaction and motivation among physicians in academic medical centers: insights from a cross-national study. *J Health Polit Policy Law.* 2008;33(6):1133-1176.
33. Committee on the Quality of Health Care in America. Crossing the quality chasm: A new health system for the 21st century. Institute of Medicine [Internet]. 2001 March 1. Available from: <http://www.iom.edu/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx>
34. Elliot-Smith S. Solving the access to care issue in Minnesota: state becomes the first to sign mid-level oral health care providers into law. *Access.* 2009;23(7):14-19.
35. Powell W, Hollis C, de la Rosa M, Helitzer DL, Derksen D. New Mexico community voices: policy reform to reduce oral health disparities. *J Health Care Poor Underserved.* 2006;17(1 Suppl):95-110.
36. Edgington E, Pimlott J, Cobban S. Societal conditions driving the needs for advocacy education in dental hygiene. *Can J Dent Hyg.* 2010;43(6):267-274.
37. Wisconsin County Health Rankings. University of Wisconsin Population Health Institute [Internet]. 2007 [cited 2011 April 16]. Available from: <http://uwphi.pophealth.wisc.edu/programs/match/wchr/index.htm>
38. Kuthy RA, McKernan SC, Hand JS, Johnsen DC. Dentist workforce trends in a primarily rural state: Iowa: 1997-2007. *J Am Dent Assoc.* 2009;140(12):1527-1534.
39. Booske B, Roubal A, Graupner A, Bergum A, Kindig D, Remington P. Health of Wisconsin report-card-2010. University of Wisconsin Population Health Institute [Internet]. 2010. Available from: <http://uwphi.pophealth.wisc.edu/programs/match/healthiest-state/report-card/2010/>
40. Peppard P, Kindig D, Remington P, Riemer A, Dranger E. Wisconsin County Health Rankings-2003. Wisconsin Public Health and Health Policy Institute [Internet]. 2003 [cited 2011 November 16]. Available from: <http://uwphi.pophealth.wisc.edu/programs/match/wchr/2003/index.htm>.
41. Sanders AE, Slade GD, Lim S, Reisine ST. Impact of oral disease on quality of life in the US and Australian populations. *Community Dent Oral Epidemiol.* 2009;37(2):171-181.
42. Tsakos G, Gherunpong S, Sheiham A. Can oral health related quality of life measures substitute for normative needs assessment in 11 to 12 year old children? *J Public Health Dent.* 2009;66(4):263-268.
43. Varghas CM, Arevalo O. How dental care can preserve and improve oral health. *Dent Clin North Am.* 2009;53(3):399-420.
44. Richards W, Harris C, Gear T. Oral health-related quality of life. *Br J Health Care Management.* 2009;15(4):181-187.
45. Humphris G, Freeman R, Gibson B, Simpson K, Whelton H. Oral health-related quality of life for 8-10 year old children: an assessment of a new measure. *Comm Dent Oral Epidemiol.* 2005;33(5):326-332.



46. Crossing the quality chasm: A new health system for the 21st century. Institute of Medicine. 2001 March 1. Available from: <http://www.iom.edu/Reports/2001/Crossing-the-Quality-Chasm-A-New-Health-System-for-the-21st-Century.aspx>
47. Steele JG, Sanders AE, Slade GD, et al. How do age and tooth loss affect oral health impacts and quality of life? A study comparing two national samples. *Comm Dent Oral Epidemiol*. 2004;32(2):107-114.
48. Sampogna F, Johansson V, Axtelius B, Abeni D, Soderfeldt B. Quality of life in patients with dental conditions: comparing patients' and providers' evaluation. *Comm Dent Health*. 2009;26(4):234-238.
49. Rublee N. Price County seal a smile dental sealant agency protocol. Department of Health and Family Service, Division of Public Health [Internet]. 2005. Available from: [http://www.cphfoundation.org/documents/PriceCountyWIOtherPHPPrevention\\_000.pdf](http://www.cphfoundation.org/documents/PriceCountyWIOtherPHPPrevention_000.pdf)
50. McGrath C, Bedi R. Population based norming of the UK oral health related quality of life measure (OHQoL-UK). *Br Dent J*. 2002;193(9):521.
51. Beazoglou T, Bailit H, Myne V, Roth K. Supply and Demand for Dental Services: Wisconsin 2010-2020. Wisconsin Dental Association [Internet]. 2010 January. Available from: [http://www.wda.org/wp-content/uploads/2012/04/Supply-and-Demand\\_Final-Report.pdf](http://www.wda.org/wp-content/uploads/2012/04/Supply-and-Demand_Final-Report.pdf)
52. Bailit H. Oral Health Education Study: Project 0913D. docstoc [Internet]. 2010 March. Available from: <http://www.docstoc.com/docs/49246066/Oral-Health-Education-Study>
53. Wisconsin Public Health Workforce 2008. Wisconsin Department of Health Services [Internet]. 2008 [cited 2011 April 6]. Available from: <http://www.dhs.wisconsin.gov/publications/P4/P45719-08.pdf>.
54. Dentist shortages for low-income populations in Wisconsin: CY 2007. Wisconsin Department of Health Services [Internet]. 2007 [cited 2011 Apr 6]. Available from: <http://www.dhs.wisconsin.gov/health/primarycare/index.htm>.
55. Adams T. Inter-professional conflict and professionalization: dentistry and dental hygiene in Ontario. *Soc Sci Med*. 2004;58(11):2243-52.
56. The Fair Labor Standards Act (FLSA). U.S. Department of Labor [Internet]. [cited 2011 November 19]. Available from: <http://www.dol.gov/compliance/laws/comp-flsa.htm>
57. BLS Information: Glossary: F. US Department of Labor Statistics [Internet]. [cited 2011 November 19]. Available from: <http://www.bls.gov/bls/glossary.htm#F>
58. Wiggins C, Hatzenbueler L, Peterson T. Hospital missions and the education of our future health care workers. *J Allied Health*. 2008;37(3):132-136.
59. Kash B, May M, Tai-Seale M. Community health worker training and certification programs in the United States: findings from a national survey. *Health Policy*. 2007;80(1):32-42.
60. Harrison R, Mitchell L. Using outcomes-based methodology for the education, training and assessment of competence of healthcare professionals. *Med Teach*. 2006;28(2):165-170.
61. Thomas H, Hicks J, Martin G, Cressey G. Induction and transition in the National Health Service for four professional groups. *Learn Health Soc Care*. 2008;7(1):27-36.
62. Dentistry examining board. Wisconsin Statutes Database [Internet]. 2011 [cited 2011 November 19]. Available from: <http://docs.legis.wi.gov/statutes/statutes/447.pdf>
63. Dentistry and Dental Hygiene - Code Book. Wisconsin Department of Safety and Professional Services [Internet]. [cited 2011 November 19]. Available from: [http://drl.wi.gov/board\\_code\\_detail.asp?boardid=13&locid=0](http://drl.wi.gov/board_code_detail.asp?boardid=13&locid=0).
64. Dental Hygienists. Occupational Outlook Handbook. Bureau of Labor Statistics, U.S. Department of Labor [Internet]. 2008. Available from: <http://www.bls.gov/oco/ocos097.htm>

## Accuracy of Digital Arm and Wrist Manometers: Clinical Implications for the Dental Hygienist

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### Introduction

Thorough patient assessment is the first step to successful treatment planning and risk management in the dental hygiene process of care. Data that indicates the physical health status of a patient must be gathered and analyzed. A key piece of determining a patient's current health status is obtaining accurate vital signs, particularly blood pressure. In addition to contributing to the picture of the patient's overall health status, the assessment of vital signs is imperative in avoiding immediate medical emergencies in the dental chair, such as myocardial infarction or cerebrovascular accident. This is especially important for a wide array of patients, such as the growing geriatric population with concomitant medical conditions, those with multiple prescribed medications, and those with uncontrolled hypertension. The risk for a medical emergency is then further compounded by the use of pharmacologic agents, such as local anesthesia or anxiety provoking procedures.

The mercury manometer is an instrument that requires skill to use.<sup>1,2</sup> However, the mercury manometer is now gradually being phased out due to a heightened awareness of mercury safety and its impact on the environment.<sup>3-5</sup> Practitioners may have the perception of this modality requiring more time and being more technique sensitive than alternative methods. In light of this, many institutions are transitioning to automated digital or aneroid manometers. In addition to being mercury-free, these devices are thought to be quick and less technique sensitive.<sup>6</sup> Observation of the investigators indicates dental hygiene education programs and dental offices appear to be following this trend. Whether it is to save time

### Abstract

**Purpose:** Utilization of digital manometers chairside is fast becoming a standard of care in dental hygiene education. It is imperative to ensure accurate blood pressure measurements regardless of modality to avoid medical emergencies in the dental chair. This study sought to determine the accuracy of the automated digital arm and wrist cuffs utilized by students in the University of Maine at Augusta, Bangor Campus Dental Health Programs' dental hygiene clinic.

**Methods:** After institutional review board approval, 121 subjects were recruited, with 21 excluded for a total of 100 subjects. Subjects were randomly assigned to different test modalities upon check-in. Initial blood pressure measurements were taken with a calibrated aneroid control device by a principal investigator. A second measurement was taken with the randomized arm or wrist manometer 5 minutes later. Investigators were blinded to the modality of test manometer and measurements obtained from the second reading. All readings were taken according to manufacturers' instructions to ensure technique consistency.

**Results:** Data indicated lower readings for each modality from the control for both systolic and diastolic measurements. The differences in the systolic and diastolic readings for the wrist modality were significantly lower than the control with ( $p=0.000$ ) and ( $p=0.000$ ), respectively.

**Conclusion:** Automated digital manometers should be used with caution as a screening tool in the dental setting, particularly when administration of pharmacological agents such as local anesthesia may be used during the course of treatment. These automated modalities should not be used for patients with cardiac or hypertensive conditions.

**Keywords:** blood pressure, dental hygiene, manometer, accuracy

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and frustration, or whether programs feel students will get more accurate readings than with an auscultatory device is not clear.

Most automated devices detect oscillation in the arterial wall as opposed to the sound of blood moving through the artery.<sup>6-8</sup> The American Association of Medical Instrumentation (AAMI) and the British

Hypertension Society (BHS) have protocols in place to validate such devices. However, not all devices on the market have been validated. Bern et al noted there is no standard algorithm in the manufacture of automated devices to identify systolic and diastolic measurements; each manufacturer uses their own unique algorithm.<sup>6</sup> The purpose of this study was to determine whether or not these modalities are a valid option for use in the dental hygiene practice setting.

A review of the literature has revealed several points relevant to this study. Accuracy in non-invasive blood pressure monitoring devices appears questionable regardless of modality. Even if a device has been validated, it does not mean that it will perform accurately in clinical use. The validation, accuracy, required techniques and special considerations for the use of non-invasive blood pressure monitoring devices will be reviewed with emphasis on automated blood pressure monitoring devices.

### **Incidence**

Obtaining vital signs, including blood pressure readings, are essential to appropriate patient care in dentistry as well as medicine. Nelson et al noted, "obtaining [blood pressure] has been identified as one of the most important measurements in clinical medicine."<sup>5</sup> The American Dental Hygienists' Association (ADHA) defined the collection of vital signs as a standard of clinical hygiene practice.<sup>5,9</sup> Therefore, it is imperative that the devices utilized in blood pressure measurement be accurate.

The most accurate means of measuring blood pressure is via a catheter placed directly in an artery.<sup>6</sup> This is not a feasible method for everyday measurement. For more than a century, practitioners have relied on mercury sphygmomanometers in order to obtain blood pressure readings. This modality requires the use of a stethoscope to listen to the movement of blood through the artery. The auscultatory piece of the mercury modality adds the disadvantage of relying on the hearing of the operator.<sup>5,10</sup> Hearing is variable amongst each operator, introducing or increasing the chance for inaccuracy. Furthermore, the recognition of the toxic nature of mercury and its accompanying environmental hazards is leading to the replacement of this modality with aneroid and automated digital modalities.<sup>3-5</sup>

Automated digital manometers have multiple benefits. There is no need for a stethoscope, as measurements are taken by detecting the movement of the arterial wall.<sup>6-8</sup> These devices are operated by the simple push of a button, leaving the clinician free to attend to other matters. Many devices

will give a pulse reading in addition to the blood pressure measurement.

The popularity of automated blood pressure devices has led to an explosion of manufacturing, with numerous varying devices being produced all over the world. A wide array of inexpensive, automated options can be conveniently purchased at drug and grocery stores. One study reported that in the UK alone there were 40 manufacturers offering nearly 100 different automated devices.<sup>4</sup> In an effort to help clinicians and institutions select devices to fit their needs, organizations such as the AAMI and the BHS have instituted protocols and standards to validate automated devices, while also testing many devices and publishing the results. When choosing a device it is recommended that selection be based on validation by the AAMI or BHS. However, these devices may be cost prohibitive in the dental hygiene educational and clinical practice settings.

### **Considerations in Practice**

Wan et al noted that a blood pressure measurement device that has received validation by the AAMI or the BHS does not necessarily guarantee clinical accuracy.<sup>1</sup> They further noted that validated devices are not necessarily more accurate than those that failed protocol validation. Calibration of the automated device is key to accurate blood pressure measurements, as well as patient safety. Uncalibrated devices increase the chances of patients being misdiagnosed as hypertensive or within healthy limits.<sup>4</sup> The clinician must also be aware that automated blood pressure devices wear out much more quickly.<sup>4,11</sup>

Several studies have noted that the technique guidelines published by the American Heart Association (AHA) should be used when obtaining automated blood pressure measurements in order to increase accuracy.<sup>1,10,11</sup> In addition, the clinician must also be aware that the automated device is not appropriate for blood pressure measurement of all patients. The use of the automated blood pressure device is contraindicated in patients with several cardiac related conditions, such as atherosclerosis, hypertension, hypotension and dysrhythmias.<sup>1-3,6,8,10,12</sup>

Clearly, ease of use does not equal accuracy. Although automated, these devices require as much attention to technique as an auscultatory method. It is critical that practitioners follow manufacturer directions for the use of automated devices. Stergiou et al noted that inappropriate cuff size can lead to overestimation and underestimation of blood pressure measurement as well.<sup>13</sup> Accurate blood

pressure measurement is important for the overall treatment and wellbeing of the patient. Although automated devices take readings at the push of a button, the clinician must give great consideration to technique, patient selection, equipment maintenance and equipment longevity.

## Methods and Materials

For this study, 121 subjects aged 18 and over were recruited from the University of Maine at Augusta Dental Health Programs' Dental Hygiene clinic patient pool at appointment check-in. Exclusion criteria included: cardiac arrhythmia, arterial stiffness, having a full bladder, trouble breathing, tobacco use, pain, arm circumference larger than 16 inches, myocardial infarction within the last 6 months, current cancer therapy and the inability to present a bare arm. A total of 21 subjects were excluded for a final sample size of 100. The sample size of 100 was determined to be a suitable size for the study by the biostatistician. Eighteen senior dental hygiene students worked with the principal investigators (PIs) on this project and were trained on how to operate each of the test modalities, and 2 dental hygiene faculty members with experience in conducting clinical research studies served as the PIs. Subject blood pressure would be obtained first with the control unit by 1 of the PIs, followed by another reading taken by a student with 1 of the test modalities. The study received approval from the University of Maine at Augusta Institutional Review Board.

An aneroid manometer (American Diagnostic Corporation® E-Sphyg2™, Hauppauge, NY) was used as the control modality for this study. Investigators took the control unit to the local medical center's biomedical engineer for calibration both before and after the study. The control unit measured at  $\pm 2$  mm Hg at both calibrations, which was well within the AAMI and BHS ranges for validity. Senior dental hygiene students were given a training session and were taught to utilize both variable modalities according to strict adherence to manufacturer instructions and study protocols and to record the necessary data.

In addition, both PIs completed a calibration exercise for inter-rater reliability. Investigators each took the blood pressure of 8 volunteers before commencing the study. These readings were taken with the control unit, strictly adhering to manufacturer's instructions and using the patient qualifying criteria. The "r" value for this reliability study was 0.898, which was deemed appropriate for this type of study and were confident to move forward enrolling subjects. The PIs conducted this exercise to determine the degree to which the investigators would be able

to obtain reliable results when using the control unit on the intended subject population. It also offered a formal protocol training session for both PIs prior to the initiation of study subject enrollment.

## Assignment

Upon obtaining consent, subjects were randomized into modality A (arm) or B (wrist) sequentially by reception staff. Data collection sheets were inserted into subject charts, indicating to students the randomized modality to be used. Investigators determined subject eligibility or exclusion once subjects were seated and medical history obtained. Once the subject was determined eligible, a PI acquired a baseline blood pressure reading with the control unit, recorded the reading and exited the operatory. The student operator would then return to the operatory, and acquire another blood pressure reading with the randomized modality after 5 minutes.

All units used in the experiment came from the manufacturer programmed for use on the left arm and wrist; all subjects had their blood pressure taken on the left arm. All readings were taken with the subject seated in an upright position, with both feet flat on the floor. Subjects were instructed to remain still, and not to speak during measurement, as this could affect the reading. All other manufacturer instructions were followed for each of the modalities.

## Analysis and Statistics

Pearson Chi-square was done to determine if randomization produced balanced groups in each of the test modalities. Differences between control measurements and variable modality measurements were tested using 2 sample t-tests. For a comparison of inter-rater reliability, the following tests were run: paired t-test, comparison of variances, Pearson correlation and concordance correlation coefficient.

## Results

Nominal variables for demographics such as age ( $p=0.151$ ), gender ( $p=0.433$ ) and randomization to each PI ( $p=0.356$ ) showed no differences in distribution. Average measurements for control systolic and diastolic blood pressure compared to age showed no difference between the two randomized groups.

Comparison of randomized group means of systolic and diastolic blood pressure to control measurements displayed mixed results. Although measurements were lower for modality A compared to the control, the values were not statistically significant.

cant. Readings fell within the AAMI and BHS guidelines with comparative means for the systolic of 129.1 mm Hg for the control, and 127.3 mm Hg for modality A ( $p=0.274$ ). Results show measurements for group B were significantly lower for both systolic ( $p=0.000$ ) and diastolic readings ( $p=0.000$ ) compared to the control measurements. Regression models show test modalities tended to be more accurate for those with lower blood pressures.

The results for inter-rater reliability showed no significant difference between the measurements of the PIs. The  $p$ -values for the paired  $t$ -test were 0.822 (systolic) and 0.803 (diastolic). For the tests of equal variances the  $p$ -values were 0.469 (systolic) and 0.201 (diastolic). The Pearson correlations were 0.898 (systolic) and 0.730 (diastolic), with the concordance correlation coefficients were 0.897 (systolic) and 0.691 (diastolic). With a 95% confidence interval for the concordance correlations, results show a concordance for both systolic (0.811, 0.945) and diastolic measurements (0.527, 0.805).

## Discussion

This study demonstrated that the automated digital modalities record lower readings than the aneroid manometer, whether arm or wrist type. These findings are consistent with the evidence discussed in the literature.<sup>7,8,10</sup> The wrist modality demonstrated lower readings well beyond accepted limits and should therefore not be considered for use in the assessment of dental hygiene patients at this time. However, these findings are based on only 2 measurements per patient. Future studies may want to include a third measurement, to follow the protocol set forth by the AAMI and BHS.<sup>14-16</sup> While the literature is conflicting in regards to the accuracy of aneroid manometers,<sup>3-5</sup> the aneroid unit utilized as the control in this study was found to be well within the range of validity both pre and post study.

The tendency to measure lower readings suggests the opportunity for misdiagnosis of the hypertensive patient. Lower measurements introduce more risk to dental treatment, increasing chances of a medical emergency in the dental chair. This may lead to a patient who should be dismissed for having a blood pressure measurement outside of treatment guidelines remaining in the chair for procedures. The risk for medical emergency may be particularly compounded when administering local anesthetic agents and nitrous oxide and oxygen sedation.

The reasons for the lower readings are not clear, but some conclusions can be drawn. The risk for operator error is always inherent. It is of note that even when using new units and following strict ad-

herence to manufacturer instructions, the test modalities still vary. However, the AHA guidelines for obtaining blood pressure measurements were not used in this study - manufacturer instructions were followed.<sup>1,10,11</sup> Dental hygiene clinics that choose to include automated arm or wrist modalities to be included in student kits should consider developing a protocol for obtaining blood pressure measurements. The protocol should combine the AHA guidelines with manufacturer's instructions. Contraindications for the use of these modalities, such as hypertension or hypotension and dysrhythmias should also be included in any protocol. Anyone utilizing these types of manometers should be aware that they come calibrated for use on a specific arm, and that acquiring a reading from the opposite arm, or following the manufacturer's directions on switching the machine to the opposite arm can introduce variance of measurements. In addition, these modalities should be stored in a way that minimizes wear and tear, as these manometers are already prone to quicker deterioration, which leads to inaccuracy. Although the literature does not suggest a time frame or number of measurements as a turning point in these manometers' lifespan, consideration should be given to replacing the units within a set time based on the patient load. Consideration should also be given to purchasing validated aneroid manometers that can be calibrated regularly.

This study may be limited by the fact that hypertensive patients were not excluded, as results showed both modalities to perform more accurately on lower blood pressure readings. These modalities are not meant for baseline assessments in the clinical setting. Although hypertension is contraindicated for the use of these modalities, other literature clearly delineates use of these manometers at home as means for hypertensive patients to monitor the control of their condition for their primary care provider. These findings indicate that their use in the clinical environment should be limited.

## Conclusion

Although both convenient in use and low in cost, automated digital arm and wrist modalities are not intended for the clinical assessment of vital signs, and therefore do not offer the clinical accuracy needed by the dental hygiene practitioner. Strict protocols should be developed for obtaining blood pressure measurements that include: AHA guidelines, manufacturer instructions and literature supported contraindications for use. Dental hygiene education programs should consider integrating an established protocol into their preclinical and clinical curriculum to ensure patient safety. Considering

the number of people in the U.S. with some form of hypertension, use of these modalities is not recommended for routine dental hygiene assessment. The purchase of aneroid or other reliable manometers that can be calibrated and serviced on a regular basis, together with strict measurement protocols can offer the safety and efficacy needed for clinical dental hygiene treatment.

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## References

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1. Wan Y, Heneghan C, Stevens R, et al. Determining which automatic digital blood pressure device performs adequately: a systematic review. *J Hum Hypertens*. 2010;24(7):431-438.
2. Westhoff TH, Schmidt S, Meissner R, Zidek W, van der Giet M. The impact of pulse pressure on the accuracy of wrist blood pressure measurement. *J Hum Hypertens*. 2009;23(6):391-395.
3. Amooore JN, Guehenec M, Scordecchia R, Scott DHT. Auditing the technology used to measure blood pressure. *J Med Eng Technol*. 2010;34(3):209-216.
4. de Greeff A, Lorde I, Wilton A, et al. Calibration accuracy of hospital-based non-invasive blood pressure measuring devices. *J Hum Hypertens*. 2010;24(1):58-63.
5. Nelson D, Kennedy B, Regnerus C, Schweinle A. Accuracy of automated blood pressure monitors. *J Dent Hyg*. 2008;82(4):1-17.
6. Bern L, Brandt M, Mbelu N, et al. Differences in blood pressure values obtained with automated and manual methods in medical inpatients. *Medsurg Nurs*. 2007;16(6):356-361.
7. Beaubien ER, Card CM, Card SE, Biem HJ, Wilson TW. Accuracy of the Dinamap 1846 XT automated blood pressure monitor. *J Hum Hypertens*. 2002;16(9):647-652.
8. Kayrak M, Ulgen MS, Yazici M, et al. A Comparison of blood pressure and pulse pressure values obtained by oscillometric and central measurements in hypertensive patients. *Blood Press*. 2010;19(2):98-103.
9. Standards for Clinical Dental Hygiene Practice. American Dental Hygienists' Association [Internet]. 2008 March. Available from: [http://www.adha.org/downloads/adha\\_standards08.pdf](http://www.adha.org/downloads/adha_standards08.pdf)
10. Chiolero A, Paradis G, Lambert M. Accuracy of oscillometric devices in children and adults. *Blood Press*. 2010;19(4):254-259.
11. Dickson BK, Hajjar I. Blood pressure measurement education and evaluation program improves measurement accuracy in community-based nurses: a pilot study. *J Am Acad Nurse Pract*. 2007;19(2):93-102.
12. Lamb TS, Thakrar A, Ghosh M, Wilson MP, Wilson TW. Comparison of two oscillometric blood pressure monitors in subjects with atrial fibrillation. *Clin Invest Med*. 2010;33(1):54-62.
13. Stergiou GS, Tzamouranis D, Nasothimiou EG, Protogerou AD. Can an electronic device with a single cuff be accurate in a wide range of arm size? validation of the Visomat Comfort 20/40 device for home blood pressure monitoring. *J Hum Hypertens*. 2008;22(1):796-800.
14. O'Brien E, Atkins N, Stergiou G, et al. European society of hypertension international protocol revision 2010 for the validation of blood pressure measuring devices in adults. *Blood Press Monit*. 2010;15(1):23-38.
15. Williams B, Poulter NR, Brown MJ, et al. Guidelines for management of the hypertension: report of the fourth working party of the British Hypertension Society, 2004-BHS IV. *J Hum Hypertens*. 2004;18(3):139-185.
16. National High Blood Pressure Education Program. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Bethesda (MD): National Heart, Lung, and Blood Institute (US)*; 2004. Report No. 04-5230.