

September 19, 2016

Martha J. Somerman, D.D.S., Ph.D.
Director
National Institute of Dental and Craniofacial Research
31 Center Drive, Room 2C39
Bethesda, MD 20892-2190

Re: NIDCR Proposed Research Initiatives for FY 2018

Dear Dr. Somerman:

On behalf of our 159,000 members, we are pleased to comment on the National Institute of Dental and Craniofacial Research's (NIDCR's) Proposed Research Initiatives for Fiscal Year 2018. We offer these comments in response to your email of August 5, 2016.

As you can see from our enclosed comments, we are generally pleased with the areas NIDCR has proposed for study: immunotherapy from head and neck cancer; implementation science and oral health; oral HIV vaccine-induced immunity; and the oral microbiome and HIV. We urge you to consider whether adequate models exist to pursue craniofacial bones and the nervous system as a research initiative at this time.

The enclosed comments reflect the views of the ADA Council on Scientific Affairs (CSA), the Association's primary agency for dental science and research considerations. The Council's review of NIDCR's proposed research initiatives includes perspectives on the initiatives and targeted areas of study. The Council also expounded on the primary dental research needs identified in the ADA's current Research Agenda, also enclosed. We would welcome NIDCR's input on the next iteration, which will be available in draft form this fall.

Developing the body of research in these areas will advance dental science and oral health care, as well as research funding for investigations on prevention and risk assessment strategies for managing dental caries, periodontal disease, and other oral diseases, including cancers of the oral cavity and oropharynx.

We appreciate the opportunity to comment on NIDCR's proposed research initiatives for FY 2018. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org. Information is also available at ADA.org/research.

Sincerely,

/s/

Carol Gomez Summerhays, D.D.S.
President

CGS:KTO:rjb
Enclosures (2)

/s/

Kathleen T. O'Loughlin, D.M.D., M.P.H.
Executive Director

This page intentionally left blank.

Technical Comments

National Institute of Dental and Craniofacial Research Proposed Research Initiatives for Fiscal Year 2018

September 19, 2016

The following sections present comments and perspectives from members of the ADA Council on Scientific Affairs regarding NIDCR's Proposed Research Initiatives for Fiscal Year 2018.

A. Immunotherapy for Head and Neck Cancers

The Council supports the development of new cancer therapies, including improved immune-directed therapies for head and neck cancer (HNC), which hold potential for prolonging patient survival, reducing adverse events, and enhancing quality of life in patients with HPV-positive or HPV-negative tumors. The poor prognosis and mortality associated with late-stage head and neck cancer underscores the need for novel and effective immunotherapeutics that can provide more individualized care, improved HNC treatment outcomes, and fewer treatment-related side effects from chemotherapy or radiation therapy.

B. Implementation Science and Oral Health

The Council supports the pursuit of behavioral science research with clinical parameters to evaluate dentists' integration and use of guidelines (e.g., for placement of pit and fissure sealants), and various barriers and obstacles that may preempt the integration of evidence-based guidance in clinical practice settings.

The ADA recognizes that stronger evidence and best practices are needed to help dentists in the process of implementing and providing evidence-based interventions in clinical practice, including expanding the use and placement of dental sealants, which have strong evidence of effectiveness but are not optimally provided to U.S. dental patients. (Note: A 2011-2012 survey found only 40.5 percent of U.S. children aged 6-11 years had dental sealants.¹)

The ADA will continue to emphasize the importance of the development of alternatives to improve the dissemination and implementation of research outcomes, as highlighted in our response NIDCR's proposed research initiatives for the Fiscal Year 2017.

C. Oral HIV Vaccine-induced Immunity

The CSA members did not provide comments or perspectives on this proposed research initiative at this time. However, the Council recognizes that NIDCR is investigating this field of study and has an active Funding Opportunity posted online.²

D. Craniofacial Bones and the Nervous System

The Council questions whether this proposed research initiative is sufficiently developed and whether there are "adequate models" to study this in a cross-disciplinary manner. Improved

models for this type of study should be supported and neuroinflammatory pathways need to be emphasized specifically.

E. The Oral Microbiome and HIV

The Council supports more detailed study and characterization of the diverse microbial communities within oral microbiome, in both healthy individuals and individuals with oral disease or infection, such as infection with the human immunodeficiency virus (HIV) as well as individuals infected with oncogenic HPV subtypes (e.g., HPV-16 or -18), which are commonly associated with HPV-positive oropharyngeal cancer.

The Council recognizes the continued research interests in vast and diverse microbial communities within the oral microbiome, and notes the publication of an article on a recent workshop that addressed this topic area.³ As noted in this article, researchers are only beginning to investigate “the constituents of our diverse microbial communities, revealing the astonishing genetic richness that is our microbiome.”

New Proposed Research Initiatives or Topic Areas for NIDCR’s Consideration (Provided by CSA Members: August-September 2016)

1. Caries management by risk assessment

The caries management by risk assessment was developed based on the evaluation of the etiology and protective factors supporting the establishment of the risk for future disease, followed by the development of a patient-centered evidence-based caries management plan. The ADA supports the need for more studies evaluating the multifactorial process of caries management by risk assessment and how to utilize this information to optimize the clinical outcomes.

2. Functional genomics for periodontal disease and dental caries.

An extension of the previous program announcement on genomic knowledge to now highlight functional genomics for periodontal disease and dental caries. Specifically, there are current NIDCR research projects that are addressing the genetic/inflammatory biomarkers for periodontal disease, which are finalizing in the near future. After those studies are completed, researchers may then need to test the various genetic/inflammatory biomarkers that are identified in specific populations.

At the same time, with several agencies collecting genetic/inflammatory biomarker data on periodontal disease, it would be useful to have an initiative to establish a biorepository on cytokines associated with periodontal disease, as an example, and those cytokines could then be tested further in clinical settings.

3. Secure continuous support to: dental caries, periodontal disease, and oral head and neck cancer research

The CSA identified dental caries, periodontal disease and oral head neck cancer as research priorities for the profession. It is important to secure the development of new methodologies to enhance the prevention, diagnostics, management and treatment of these priorities supported by basic and clinical outcomes.

¹ Dye BA, Thornton-Evans G, Xianfen L, Iafolla T. Dental Caries and Sealant Prevalence in Children and Adolescents in the United States, 2011–2012. NCHS data brief, no. 191. Hyattsville, MD: National Center for Health Statistics. 2015. http://www.cdc.gov/nchs/data/databriefs/db191_table.pdf#4

² Oral HIVacc: Oral Mucosal Immunization Approaches for HIV Prevention (R01). <http://grants.nih.gov/grants/guide/rfa-files/RFA-DE-16-006.html>

³ Moyes DL, Saxena D, John MD, Malamud D. The gut and oral microbiome in HIV disease: a workshop report. *Oral Diseases* 2016; 22 (Suppl. 1): 166-170. <http://onlinelibrary.wiley.com/doi/10.1111/odi.12415/epdf>

This page intentionally left blank.

RESEARCH OF IMPORTANCE TO THE PRACTICING DENTIST, 2015-2016

Mission Statement

A major objective of the ADA is to promote a good quality of life by improving the oral health of the public and encouraging optimal health behaviors. To achieve this objective and to support the ADA's goal to be America's leading advocate for oral health, it is imperative that the ADA take a leading role in promoting, conducting and critically reviewing research on topics related to dentistry and its relationship to the overall health of the individual. The ADA should serve as a facilitator of the national dental research effort, identify priority topics for research, and ensure the timely dissemination of information to the profession.

STRUCTURE OF THE ADA RESEARCH AGENDA

The Research Agenda targets three to five primary goals that remain consistent for at least two years as targeted research priorities. The corresponding objectives are reviewed biennially. Updates are based on emerging research needs and input from members on priority clinical topics in dentistry.

RESEARCH AGENDA TOPICS

Goal 1: To understand the social, behavioral and biological determinants of oral and dental diseases and their impact on the provision of dental care.

Objective 1-1: Evaluate the application of risk assessment, risk communication and other risk management strategies (including development and/or validation of evidence-based risk assessment instruments) in the diagnosis and treatment of pediatric and adult caries, periodontal diseases, and mucosal diseases including oral cancer, and their effectiveness in improving oral health outcomes.

Objective 1-2: Enhance understanding of factors related to access to—and utilization of—dental services across the age spectrum, from pediatric to geriatric populations, with emphasis on the development and evaluation of innovative methods to:

- prevent or reduce early childhood caries in at-risk populations;
- increase oral health literacy of the public, including its relation to overall health;
- evaluate and report the impact and effectiveness (outcomes) of health literacy interventions, including those targeting dentists and their team members; and
- address oral health disparities and improve access to oral health care in the United States.

Objective 1-3: Investigate and develop therapies for the prevention, reversal and non-surgical management of dental caries in all age groups.

Goal 2: To understand the scientific basis of emerging issues and therapies of interest to the practice of dentistry.

Objective 2-1: Evaluate the safety and effectiveness of new and existing diagnostic, therapeutic and cosmetic products, methods, instruments and technologies used in dentistry through longitudinal assessment of safety and patient outcomes, including pre- and post-market studies. Examples of priority topics to help inform clinicians include but are not limited to:

- determine the effectiveness of visual/tactile examination and adjunctive devices and/or procedures for detection of pre-malignant/malignant lesions, and evaluate the impact of adjunctive detection devices and/or techniques on patient outcomes;
-

- evaluate the safety and diagnostic efficacy of cone beam computed tomography or other emerging imaging technologies versus standard radiography for dental applications;
- research on the short- and long-term safety of tooth whitening products and procedures;
- laser therapies, biomimetic materials and other novel restorative materials.

Objective 2-2: Investigate, develop and clinically evaluate therapies and therapeutic materials appropriate for prophylaxis, tissue engineering, healing and/or regeneration of diseased teeth, bone structures and soft tissues of the oral cavity.

Objective 2-3: Evaluate the impact of dental practice, materials and products on human health and the environment.

Goal 3: To conduct research in support of the application of evidence-based dentistry.

Objective 3-1: Develop, test and validate methods for assessing outcomes related to the use of evidence-based clinical recommendations and clinical practice guidelines in dentistry.

Objective 3-2: Develop and implement improved methods and processes to increase the impact of dental practice-based research networks as a means to address clinically relevant research questions and promote collaborative investigations of preventive and therapeutic interventions that support the advancement of oral health care.

Goal 4: To understand the scientific basis of the relationship between oral health and systemic conditions, and to evaluate the impact of dental interventions on these systemic conditions.

Objective 4-1: Investigate how oral and systemic conditions and diseases affect each other to determine causality and the effect of therapies on clinical outcomes of both the oral and systemic health of the patient.

Objective 4-2: Investigate the uses of non-invasive salivary and oral fluid diagnostics to assist in the early detection and surveillance of oral and systemic conditions, with emphasis on elucidating the scientific basis for detection of systemic diseases in saliva.

The American Dental Association's most important scientific responsibilities are in the area of knowledge and technology transfer and in assuring that the profession is kept abreast of scientific and technological advancements. With this in mind, the Council on Scientific Affairs develops a biennial Research Agenda to identify the critical research needs of today's practitioners, and to advance scientific research on the highest priority treatment-oriented topics, and emerging issues of importance in the management of oral diseases. The Council believes that these issues have short- and long-term impact on the quality of patient care and the continuing development of dental practice. The Council wishes to make clear that the Research Agenda is not exhaustive, but rather highlights priority topics that are directly related to patient care, answerable, and likely to significantly impact the practice of dentistry.