The TMJ Association, Ltd.

TMJ News Bites

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Moving TMJ Research into the 21st Century – At Last!

Background

The National Advisory Dental & Craniofacial Research Council meets periodically to receive state-of-the-Institute reports from the National Institute of Dental and Craniofacial Research (NIDCR) Director, other staff, and guest scientists to learn about proposed new policies, activities, and research concepts in a public session. In a closed session, Council provides a secondary review of the research project grant applications the Institute proposes to fund. Concurrence by a majority of the Council is needed for implementation of grant funding and for approval of new policies and concepts.

The TMD IMPACT Concept Proposal

On January 25, 2022, the 229th meeting of the Council convened to review a series of "Concept Clearances," research initiatives deemed to be of high priority to the Institute. One proposal was to establish a **TMD Collaborative for Improving Patient-Centered Translational Research (TMD IMPACT)**. What followed was an outline of research goals and projects to: "advance Temporomandibular Disorders (TMD) basic and clinical research, research training and translation to evidence-based treatment and improved clinical care - through the establishment of a national, interdisciplinary, trans-NIH, patient-centered research Collaborative." This proposed Collaborative would include relevant research areas from tissue engineering and regeneration, TMD pain, disease prevention, building the evidence base for existing treatments, and developing scientifically based new treatments.

The Concept was presented by Melissa Ghim, PhD, Director of the Institute's Extramural Neuroscience, Orofacial Pain and Temporomandibular Disorders Program. She emphasized the multidisciplinary nature of the Collaborative as well as the multidisciplinary composition of the teams that would carry out the research, which would include consideration of co-occurring pain and non-pain conditions associated with TMDs. Implicit in that statement is the Institute's recognition that TMDs are complex multifactorial disorders, *not* dental conditions mainly treated by dentists.

Equally important, Dr. Ghim went on to say that the proposed Collaborative will be patient-centered, recognizing the extent of the problem and the pressing need to find effective treatments for TMD patients.

Dr. Ghim acknowledged that research on the temporomandibular joint and TMDs has lagged behind research of other musculoskeletal conditions and also noted the slow pace of development of TMD therapies/pain drugs.

TMD Research Opportunities

Overall, she said the proposed Collaborative offered opportunities to:

- Build a coordinated multi- and interdisciplinary platform to support large-scale studies, which integrate across studies and projects, and provide a cohesive research strategy/agenda
- Employ systems biology and whole-person approaches, including biopsychosocial factors and comorbidities
- Coordinate data repositories and centralize data resources
- Develop teams of multi- and interdisciplinary investigators

Specific TMD Research Projects

Following those broad aims Dr. Ghim went on to list specific research projects that may be pursued to:

- Understand the mechanistic underpinnings of TMD for specific patient subgroups and phenotypes and to identify and validate etiologic targets
- Establish best practices for integrated clinical management in the context of co-occurring pain conditions and comorbidities
- Develop tools and technologies to facilitate access to the temporomandibular joint and associated tissues to improve upon current diagnostics and quantitative measurement
- Use artificial intelligence, machine learning, and deep learning to integrate data from animal studies, basic and clinical research to aid in the development of individualized clinical decision making and predict patient outcomes
- Strengthen the evidence base for treatments and interventions
- Develop evidence-based early diagnosis and prevention strategies

Possible Organization of a TMD Collaborative

Dr. Ghim touched briefly on how the proposed Collaborative might be organized. In one configuration a series of centers would be established each with interdisciplinary teams, all tied to a central coordinating hub. A second possibility would be to have clusters of specialized interdisciplinary centers, each tackling different parts of a comprehensive TMD research agenda. The basic point of adopting a center approach, she said, was the belief that the whole was greater than the sum of its parts: that bringing together complementary resources and disciplines and diverse ways of thinking can deliver over and beyond what single investigators can do.

Comments by Advisory Council Members

She then turned discussion of the proposal over to two members of Council who had been previously briefed on the Concept and tasked with providing comment. Dr. Clark Stanford, Dean of the University of Illinois at Chicago College of Dentistry noted that the proposed Concept reflected the

recommendations from the comprehensive report of the National Academy of Medicine (NAM) – *Temporomandibular Disorders: Priorities for Research and Care, specifically* "to create and sustain collaborative and multidisciplinary research on TMDs …through a national collaborative research consortium." He said he had been co-chair of the multi-council working group which was tasked to respond to the NAM report. He also paid tribute to the late Dr. William Maixner who directed the multi-centered Orofacial Pain: Prospective Evaluation and Risk Assessment (OPPERA) epidemiological study of TMDs for generating the most significant findings about the disorders to date. He enthusiastically supported the collaborative Concept, making an especially strong case for **including Patient Advocacy groups from the start**. Their voice needs to be heard, he said, not only in terms of outcome measures, but also, given the power of social media, in getting the correct scientific messages out to the public. "And so patient-related communication is something I would strongly recommend be included in the design of the Consortium from Day One. Another key element is the training needed for investigations in complex areas like chronic pain and the disabilities that can be associated with TMD, and that is why the Concept of a Consortium is critically important, in my opinion, to move forward, and I strongly urge Council to endorse it."

The second Council member to comment was Dr. Kathryn Albers from the Center for Neuroscience, University of Pittsburgh School of Medicine. She agreed with everything Dr. Stanford had stated and added, "There is such a strong need in terms of clinical outcomes and at the basic science level. We just don't know enough about this complex joint and how often these conditions intersect with other inflammatory conditions in the body. So, this would be an opportunity to determine what types of patient subgroups are out there and relate back to basic science studies to develop effective approaches to deal with the subgroups. I know several people with TMD and I have asked them if they were treated and did the treatment help. And the answers were No! and No! So, I am strongly in support of the Concept."

Discussion of the Concept was then open to comments and questions from other Council members. This elicited a comment from one member who recommended that sleep problems be included in the TMD research agenda. He was aware that treatment for sleep disorders like sleep apnea could ameliorate some TMD issues and could also reduce bruxism.

With no further discussion the Council voted unanimously to approve the Concept.

Thoughts From the TMJA

The TMJ Association (TMJA) strongly supports this Concept. And why? Because this Concept will address the need for the science that will provide evidence of safety and efficacy underlying TMJ treatments. As everybody has known for decades and the National Academy of Medicine confirmed the research results underlying TMJ treatments, “are inadequate and are of poor quality for most treatments for temporomandibular disorders (TMDs). Systematic reviews and methodologically rigorous new studies are needed.” Some examples include:

- “**Self-management and patient education** can be important components of care of temporomandibular disorders (TMDs). People with TMDs need access to self-management resources, including formal training. Research is needed to test and refine self-management interventions in order to identify which techniques are most effective, to determine which patients are most likely to see benefits, and to understand the mechanisms of self-management for TMDs.” (NAM report, 5-211)
- “Some elements of **physical therapy—including exercise and manual therapy**—have been shown to improve pain and functional outcomes for individuals with temporomandibular disorders (TMDs). However, many of the studies are of low quality and further research is needed to support the use of these treatment modalities.” (NAM report, 5-219)
- “There are **no drugs** specifically approved by the FDA for this disorder, and the evidence for efficacy of many of the recommended treatments is weak.” (NAM report, 5-221)
- “**Intraoral splint therapy** may confer a small benefit for the management of pain in individuals with TMDs, but the evidence for this is generally poor and mixed.” (NAM report 5-216)
- **Botulinum toxin Type A** is a treatment that has recently been zealously embraced as a treatment for TMD without conducting clinical trials.

"Some studies have reported improvement in facial pain in some patients with TMDs from botulinum toxin Type A injection into the muscles of mastication, but others have reported equivocal results; the data are limited and often of poor quality. There is concern for the health of the TMJ in humans using botulinum toxin Type A in the long term given the osteoporotic condition of the TMJ in rabbits." (NAM report, 5-224)

- "The NIDCR still cautions patients about **surgical** approaches to treating TMDs, stated that the treatments are "controversial, often irreversible, and should be avoided where possible." (NAM report, 5-228)

TMJA Advocacy Efforts

When The TMJ Association began, the harm caused to TMJ patients by treatments that lack scientific rigor and hearing from patients that jaw issues were just one of several health conditions patients were living with, prompted us to view TMJ as more than teeth and jaws. Recognizing the stagnant and narrow state of scientific research in this field, the TMJA organized 8 scientific meetings, beginning in 2000, which were co-sponsored by the NIH and reflected a broader scope of viewing TMJ with an interdisciplinary scientific approach needed to advance research in this field. To date we have secured 29 consecutive years of Congressional appropriations report language directing the NIH to increase funding and improve the quality of research on TMJ. Recognizing the large number of comorbid pain conditions TMJ patients experience, we established the Chronic Pain Research Alliance to promote integrated research to find the commonalities among them and uniqueness to each. We are adding other conditions to our research list as we continually find papers on an array of medical conditions associated with TMJ. These will serve as a catalyst to include TMJ in the research portfolios of Institutes whose scientific expertise is pertinent to these new findings. The Concept of bringing the scientific expertise and resources from the various institutes across the NIH addresses the complexity of TMJ.

Current TMJA Projects

The TMJ Patient-led RoundTable began in 2016. It is the first-of-its-kind, public-private collaboration of TMJ stakeholders under the auspices of Medical Device Epidemiology Network (MDEpiNet) with the backing of the FDA. The RoundTable is patient-centered. Patient's opinions and concerns are paramount. We started the RoundTable with a need to find out why some TMJ patients improve with implant surgery, while others worsen. It evolved into a far more comprehensive study of all aspects of TMJ affecting patient treatment outcomes. The goal is to establish a scientifically valid roadmap that can reliably predict treatment outcomes for individual patients. Currently we are developing common data elements for use in the first international TMJ patient registry including Patient Reported Outcomes.

The NIH and NIDCR contracted The National Academy of Sciences, Engineering and Medicine (NAM) to conduct a study of *Temporomandibular Disorders (TMD): From Research Discoveries to Clinical Treatment.* This study covered many aspects of TMJ as did the resulting recommendations. The current NIDCR Concept is, in part, based upon these recommendations. The NAM report evolved after several years of advocating to elected officials, the NIH and NIDCR the need for this type of study. The report reflects the current state of TMJ and provides 11 recommendations, which if implemented, would greatly improve the care of patients. We will be focusing our efforts going forward to see that these important recommendations are carried out.

Next Steps

Several years ago, following our first RoundTable meeting, a government agency staffer said, “TMJ is a case study in how every entity fell down on their job of protecting the TMJ patients of this country.” It seems like an eternity that the TMJA has been attempting to make TMJ patient’s situation in this chaotic and controversial field understood and acted upon by policy makers. Implementing this Concept and acting upon the other NAM recommendations tells us we not only have been heard but understood by NIH officials.

The TMJA commends Dr. Rena D’Souza, the Director of the NIDCR, for taking the recommendations of the NAM report seriously and guiding this Concept through the NIDCR Scientific Advisory Council to its approval. We are now anxiously awaiting the detailed development of this Concept which we have been promoting for decades.

We are pleased that patient-centeredness is to be the focus of the NIDCR initiative, the importance of which was stressed by both Drs. Stanford and Ghim in their comments to the Scientific Council. Patients are the experts in their condition and both the research and clinical communities have much to learn from them and their expertise is reflected in this Concept.

About The TMJ Association...*Changing the Face of TMJ*

The TMJ Association, Ltd. is a nonprofit, patient advocacy organization whose mission is to improve the quality of health care and lives of everyone affected by Temporomandibular Disorders (TMJ). For over 30 years, we have shared reliable information on TMJ with people like you. We invite you to visit our website, www.tmj.org.

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