

TMJ Patient RoundTable Project: Status Update

The TMJ Association is acting as the catalyst to develop the TMJ Patient RoundTable, a broad initiative to advance the interests of patients with temporomandibular disorders (TMD). It encompasses collaborations with all stakeholders and others whose expertise will be valuable to this project:

- Temporomandibular disorder patients
- Food and Drug Administration (FDA)
- National Institute of Dental and Craniofacial Research (NIDCR)
- Agency for Health Care Research and Quality (AHRQ)
- American Association of Oral and Maxillofacial Surgeons (AAOMS)
- Device manufacturers (TMJ Concepts, Zimmer/Biomet and Nexus)
- Basic and clinical researchers (academicians)

Collectively, these groups provide expertise in biomaterials and biomaterial sensitivity, infection, immunity, bioengineering, women's health issues, genetics, neuroscience, patient-centeredness, insurance practices, nutrition, bioethics—just about every area that affects the TMJ patient.

The TMJ Patient RoundTable is also the first patient-led project to be conducted under the auspices of the Medical Device Epidemiology Network (MDEpiNet), a public-private partnership developed to bring real-world data-patient experiences together with a broad array of experts to conduct studies aimed at improving outcomes for implant patients worldwide. The unique aspect of the RoundTable initiative is its patient-centeredness and in that regard, we expect to involve **you**, the TMJ patients, in aspects of the project as it unfolds.

The TMJ Patient RoundTable was initiated by a need to find out why some TMJ patients have successful outcomes from implant surgery, while others do not. It has evolved into a comprehensive study of all aspects of temporomandibular disorders and how these various aspects interact to affect patient outcomes. The goal is to establish a scientifically valid road map that can reliably predict treatment outcomes for individual patients. The long-term goal seeks to incorporate different study topics into the project as it evolves over time.

The first TMJ Patient RoundTable meeting was held on June 16, 2016, at the FDA headquarters in Silver Spring, Maryland, and was [reported on in the July 2016 issue of TMJ News Bites](#). That meeting led to the formation of four Working Groups to address specific areas of study and a Steering Committee to coordinate and oversee the project as a whole. In keeping with the principle of patient-centeredness, TMJ patients are members of the steering committee, the working groups, and are also co-chairs of the working groups.

Science Review Working Group. The first Working Group, co-chaired by Dr. John Kusiak, Acting Deputy Director, National Institute of Dental and Craniofacial Research, and Ms. Christin Veasley, a TMJ patient and Co-Founder and Director of the Chronic Pain Research Alliance, an initiative of The TMJ Association, are reviewing the existing scientific literature and assessing the current state of science on TMD. This includes the natural history of the condition, risk factors, and known biomarkers (genetic, biochemical, immunological, etc.) related to TMD. The objective is to determine whether factors within a person's physiology, lifestyle, or genetic makeup can predict the outcome from TMJ treatments, especially those that are invasive. Because women are most affected by TMD, special attention will be paid to studying the role of sex hormones in the response of these patients. In brief, looking at TMD as a whole, we can develop criteria, such as a particular set of symptoms, specific genetic and physiological measurements, etc., that will enable us to classify patients into subgroups, and in this way determine which patients will likely benefit, and which patients will not, from a particular TMD treatment and even be harmed from it.

Another area of study of this Working Group will be the nutritional impact on the overall health of a TMJ patient. Clearly, when pain and/or jaw dysfunction affect what one can eat, chew, or swallow, one's nutrition is compromised.

Patient-reported Outcomes Working Group. Group 2, co-chaired by Dr. Joel Gagnier, Assistant Professor, Department of Orthopedic Surgery, Assistant Professor, Department of Epidemiology, School of Public Health at the University of Michigan, Ms. Tricia Kalinowski and Ms. Michele Kaseta, TMJ implant patients, will identify articles in the scientific literature evaluating Patient Reported Outcomes (PRO) measures regarding the effects on quality of life and the safety and effectiveness of TMD treatments. They will also solicit information directly from TMJ patients using various formats. The results of their research will enable them to make recommendations on how PRO measures can be used to guide future decision-making, based upon certain established criteria for premarket and postmarket evaluation of TMJ implant devices and other therapies.

Current Protocols Working Group. If patients are experiencing adverse effects of treatments, is it because providers are treating TMD patients according to protocols and standards that are *not* based on scientific evidence of safety and efficacy? Or is it because there are no protocols or directives based on clinical studies? Members of Working Group 3 will collect and compile currently available best practices, clinical practice guidelines, and diagnostic and treatment protocols, which currently guide

clinical treatment of TMD. The co-chairs, Dr. Charles Greene, Clinical Professor of Orthodontics at the University of Illinois and Ms. Michelle Reardon, a patient herself and a mother of a TMJ patient, have already provided the Steering Committee a draft of their report. However, they are continuing to search for additional documents within other health care disciplines for example, chiropractic, physical and nutrition therapies and medical specialties such as primary care, internal medicine, neurology, and otolaryngology.

This working group will also evaluate professional organizations' codes of ethics and their stated duties to patients, as well as ethical issues in TMD health care, health science and health policy. The patients' responsibilities as clinical trial participants and implant recipients will also be examined.

Patient Scenarios Working Group. The patients' narratives that were presented at the June 16 meeting made the importance of "starting at the beginning" clear to the TMJ Patient RoundTable Planning Committee. The patients described their road to invasive procedures and implants as beginning with typical TMD treatments, including splints, grinding down teeth to adjust the bite, arthrocentesis, Botox or steroid injections, or psychoactive drugs such as anti-depressants. Either the treatment didn't work, or it worsened the condition, or the patient was misdiagnosed. Therefore, in order to learn if routine TMD treatments play a role in disease progression, the Roundtable saw the need to determine which treatments are routinely recommended for patients, examine the scientific evidence of their safety and efficacy, and explore patient-reported outcomes. And because the TMJ Patient RoundTable project is patient-centered, learning the real-world experience of these treatments from the patients themselves will be a focus of the investigation. This is the task of Working Group 4, chaired by Ms. Michele Kaseta and a co-chair yet to be determined.

Findings. We expect several outcomes from the TMJ Patient RoundTable project. One is that by its completion, we will have amassed data covering the many aspects of TMD studied by the four Working Groups. This will enable identification of the gaps in knowledge, science and practices and enable research agencies, investigators, and the clinical community to develop means to address them. Because patients' real-world experiences will be an integral part of this project, their needs and experiences will be included in treatment practices, policies, research, and directives resulting from this project

The project has been gaining momentum this year. Three of the four Working Groups are up and running, and we expect to have a white paper draft of the current projects by year's end. The focus will then turn to developing future directions of the Working Groups.

Since the start of The TMJ Association, we have advocated for many parts of the TMD problem, but this is the first time that the entirety of this complex condition is being addressed in a multidisciplinary manner led by the patients. Because, as we stated earlier, this project is patient-centered, **your** input will be solicited as we move forward. There will be questionnaires we will ask you to answer and your opinions will be

solicited on various topics. We will continue to update you on the progress of the project in our *TMJ News Bites* and website.

This is an enormous project which will benefit all patients, current and future. All of the participants are contributing their expertise pro-bono.

Finally, we present to you several of the project documents and presentations.

- [TMJ Patient RoundTable Goals and Objectives](#)
- [TMJ Patient RoundTable Steering Committee and Members](#)
- [MDEpiNet Mid-Year Update Webinar - Patient-led Translational Work TMJ Patient RoundTable, May 16, 2017 \(PowerPoint\)](#)
- [FDA/CDRH Epidemiology Grand Rounds - Overview of TMD and History of TMJ Replacement, May 18, 2017 \(PowerPoint\)](#)

Support Our Work

The TMJ Association (TMJA) is the only patient advocacy organization fighting for the best science that will lead to a greater understanding of Temporomandibular and related disorders, as well as safe and effective treatments. We cannot *change the face of TMJ* without YOU.

[Click HERE to make a tax-deductible online contribution today!](#)



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 (TMD). For over 25 years, we have shared reliable information on TMD with people like you. We invite you to visit our website, www.tmj.org.

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