MDEpiNet Annual Meeting, Silver Spring, MD

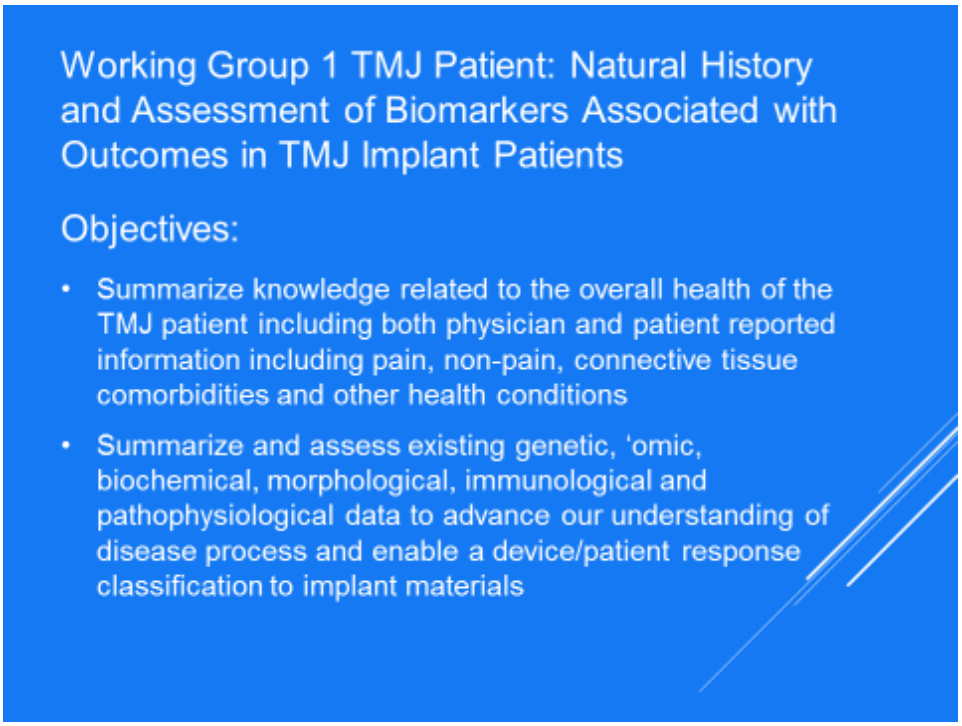
Presentation by Terrie Cowley, Oct 23, 2019

The TMJ Patient-Led RoundTable evolved from conflicting reports on TMJ implant devices. Manufacturers, surgeons, and publications claimed that patients improved after receiving implants. But reports on FDA's MedWatch system, stories on social media, and information The TMJ Association received told a different story. Patients' told of implant dysfunction, craniofacial degeneration, increased intractable pain, infections, material sensitivity, numerous revision procedures and other treatments and especially the onset of new medical conditions. These were not surprising implant outcomes as a material, Teflon-coated Proplast, cleared in 1983 to be used to replace the disc between the condyle and skull, ended up working through the skull into the brains of patients. As years went by and patients increasingly interacted in chatrooms and were connected to others by The TMJ Association, their frustration, disillusionment and distrust of the entire TMJ ecosystem became wide spread.

In 2011, the FDA issued a 522 order following a MedWatch analysis of TMJ implant reports which found 52 percent had to be explanted within the first three

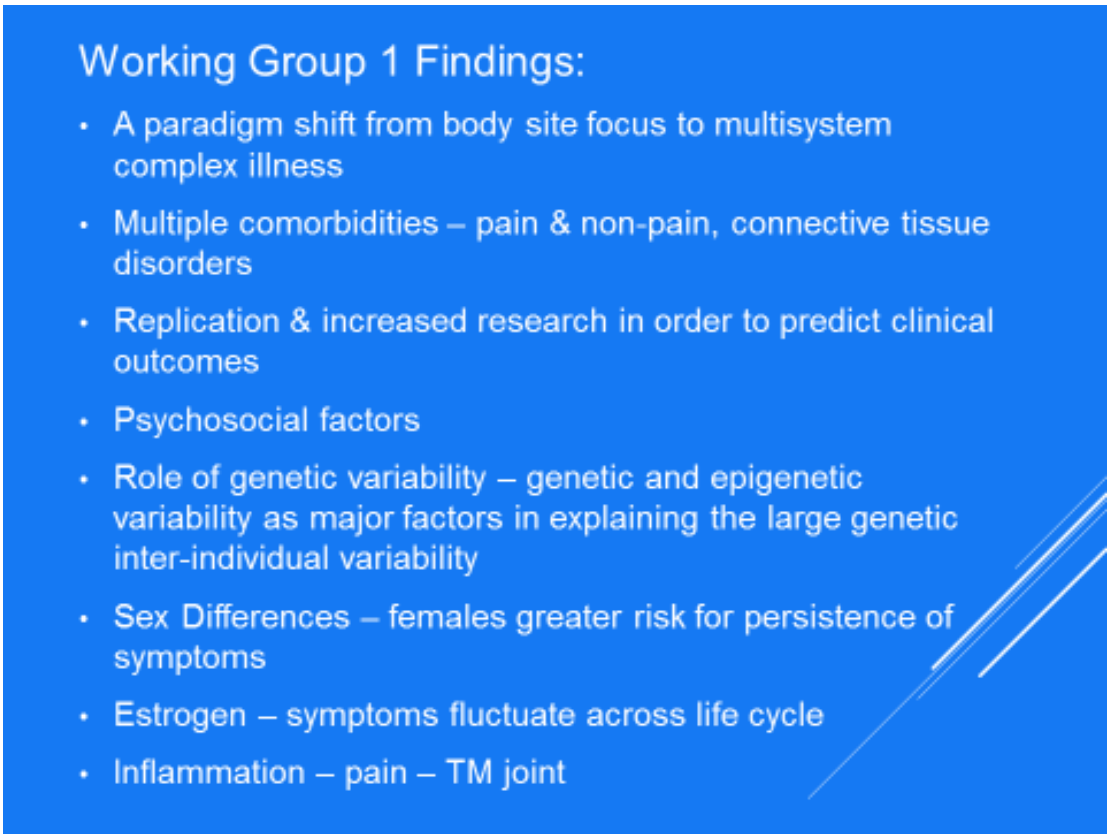
years due to severe pain and implant problems. It worth noting that the majority of TMJ patients are women between puberty and menopause.

By 2011, when the 522 order was issued, The TMJ Association recognizing the hostile environment in the TMD arena, initiated efforts to formalize a way to bring all stakeholders together with the goal of improving the healthcare of TMJ patients. The TMJ Patient-Led RoundTable formally began in 2016. Four working Groups were formed to assess key aspects related to implant success or failure. One major goal of course was to develop a TMJ implant registry, but another important goal was to ascertain ways to determine which TMJ patients did well on implants and which didn't and WHY (Group 1 goal).

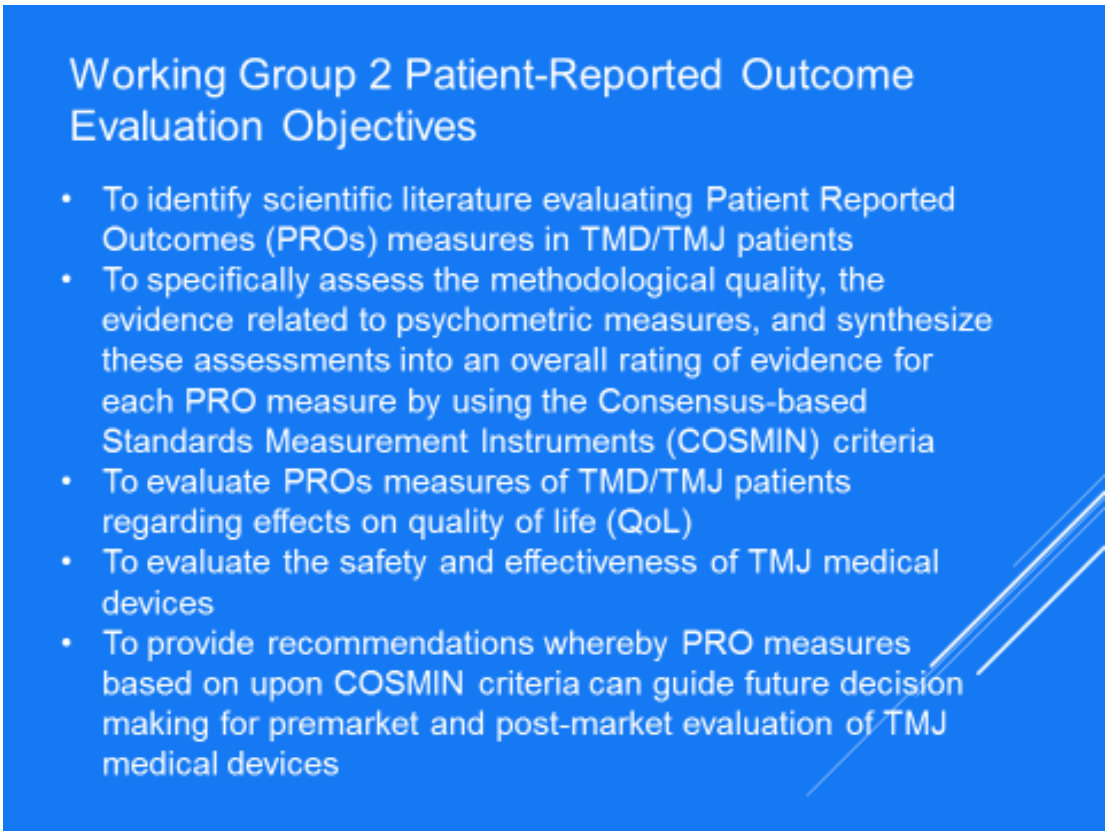


We first explored the state of TMJ science to see if the patient's physiology could be predictive of their responses. Could biomarkers be identified? This was prompted by a study published by Sidebottom in the UK which found 39% of TMJ patients were sensitive to implant materials. It was also a result of the OPPERA study which demonstrated TM disorders to be a complex, multisystem condition not as a localized pain condition.

As with many complex diseases, the RoundTable Working Group 1 found that we did not have the science to determine who will benefit and who will be harmed from a TMJ implant.

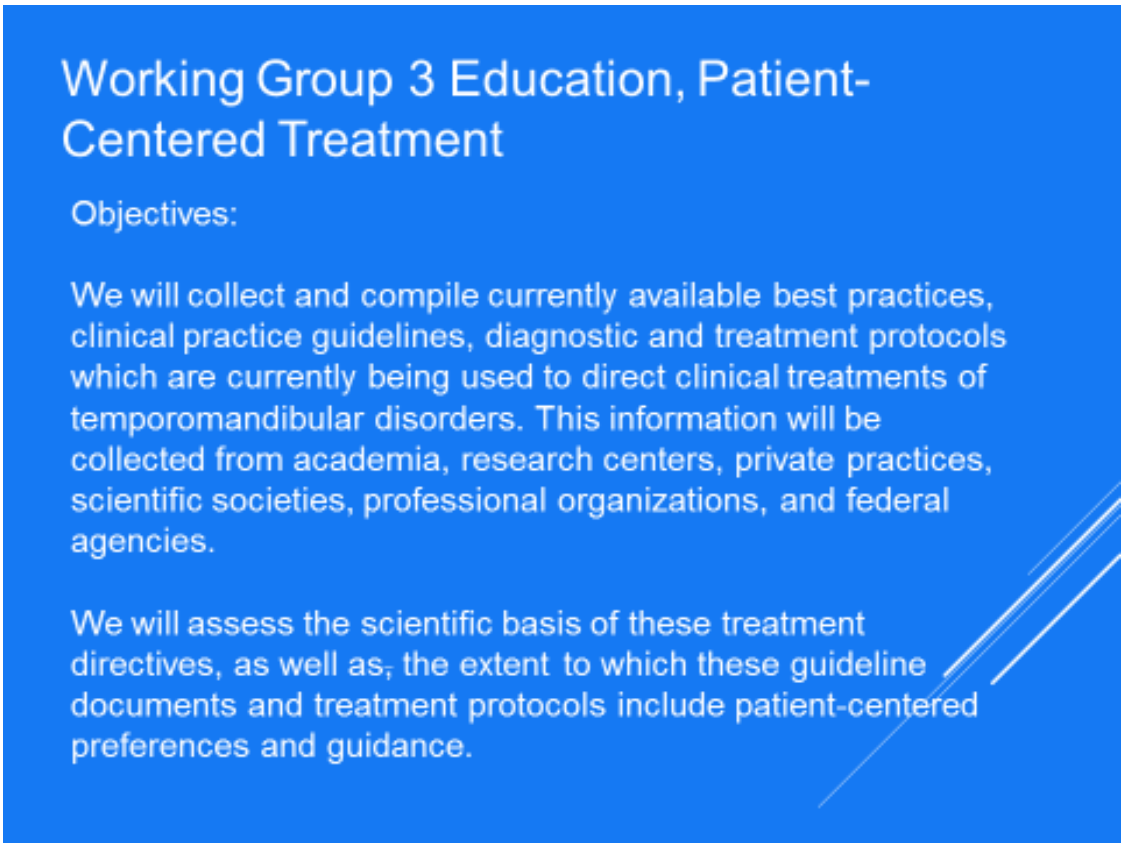


Because of the conflict between what the patients were experiencing and what professionals called success, Working Group 2 was formed to explore the literature evaluating Patient Reported Outcomes.



There were few PROs and most focused on sleep issues. Issues of importance to patients were lacking.

We then wondered about the quality of professional education and training, what guidelines direct them in performing their treatment procedures. Were they patient-centered and evidence-based?



The RoundTable Working Group 3 found there were 24 dental organizations each claiming their way was the right way to treat TMD and there were NO formal guideless, best practices, standards of care governing all TMJ therapies. And though parameters of care were just drawn up by the oral surgeons, formal guidelines and standard protocols for implant procedures and pre/post-operative care are lacking. There is NO mandate for evidence-based teaching in dental education though TMD is turfed to dentistry and there is NO specialty of TMD in dentistry.

Working Group 3 Findings:

- Though turfed to dentistry there is No Specialty of TMD in dentistry
- There are No mandate for evidence-based teaching in dental schools
- There are No formal guidelines, best practices, or standards of care established governing therapies
- There are No standard protocols for implant procedures and pre/post operative procedures
- 24 groups each claim their way to treat TMD is best
- Though science has shown TMD to be a complex multisystem condition, medical professionals learn nothing about TMD, TMJ implants, and related medical issues.

Working Group 4 Real-World Evidence and Patient Data Objectives:

- To assess the current availability and ability to identify, collect, and compile information related to selected aspects of TMJ patients' therapies.
- Develop methodologies to collect such information from sources outside of traditional clinical trials, such as prospective observational or registry studies, retrospective database studies, case reports, administrative and healthcare claims, electronic health records, registries, and social media patient networks and patient advocacy organizations.
- Evaluation of data used in support of premarket approvals

Working Group 4 Objectives:

- Develop a standardized data infrastructure for capturing patient-generated data, physician experience, and other healthcare ecosystem data necessary to better understand the disparate treatment pathways and outcomes that patients experience
- Change clinical trial practice to incorporate patient preference and real-world experience into FDA-regulated and public health trials, beginning with medical devices as a stepping stone to all treatments for TMD.
- Make the patient-reported outcomes, preferences, and other scientifically-robust patient-centered data available for inclusion in future clinical trials and surveillance efforts for all TMD treatments

The working groups undertook research for two years with patients working alongside professionals and the results were presented at the May 2018 meeting. The RoundTable members developed a whitepaper containing the results of the Working Group's research along with next steps to address the gaps identified through the research - state of science, treatment, professional education, and patient reported outcomes. This was the first compilation of such information and became the evidence for initiating a National Academy of Medicine TMD study. Patients worked alongside professionals and the importance of this cannot be understated.

The RoundTable is an ongoing project and the stakeholders are committed to continue moving forward together. Working Groups are now engaged in the projects that were planned at the May 2018 RoundTable meeting based upon the gaps identified in the Working Group research presented at the meeting.

Despite the dismal state of science in the TMJ field, some important things have been learned and advanced by the RoundTable. The most important and unique feature of the RoundTable is that it was developed based on a patient centered approach. Patients are co-chairs of the Steering Committee, and every working group. Patients are included on those committees. They have a vital role in

keeping stakeholders grounded to patients' needs and concerns. The patients come to the table as experts not only by their TMD experience but by researching the publications, and bringing their professional backgrounds to the table.

Perhaps the most important result of the RoundTable is that in bringing together all stakeholders we have broken down the silos separating government agencies, professional organizations, scientists, clinicians, manufacturers, from each other but most importantly, the patients are partners in their care.

In the '90s the Human Development Report of the United Nations stated: "People today have an urge – an impatient urge – to participate in the events and processes that shape their lives…this resource can become a source of tremendous vitality and innovation."