

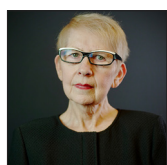
SPECIAL COLLECTION

VIEWPOINTS APPLIED PUBLIC HEALTH

Real-World Evidence: Why Are We Still Waiting?

Terrie Cowley¹, Allen W. Cowley, Jr., PhD^{1,2}

¹The TMJ Association, Milwaukee, Wisconsin, United States; ²Medical College of Wisconsin, Milwaukee, WI, United States.



***Corresponding author:**

Allen W. Cowley,
The TMJ Association,
Milwaukee,
United States.

info@tmj.org;

Received: 18 February 2025

Accepted: 26 August 2025

Published: 20 December 2025

DOI

10.25259/IJTMRPH_18_2025

Quick Response Code:



ABSTRACT

Temporomandibular disorders have a significant impact on patients. Accelerated pathways for medical products have sped access to new medical products but have not come with better post market data as was promised by law and policy. Real-world evidence is still not available to evaluate medical products to treat patients with temporomandibular disorders. The coordinated registry networks offer a strong base for producing useful evidence but require more investment.

Keywords: Coordinated Registry Networks, High-quality Data, Quality of Care, Real-world Evidence

INTRODUCTION

Temporomandibular disorders (TMD) represent a profoundly challenging and often misunderstood set of conditions that deeply impact the lives of millions. As patients and advocates, we are deeply grateful to the editors of the *International Journal of Translational Medical Research and Public Health* for this opportunity to raise an urgent issue: the need for better evidence.

Patients understand that medical advancements carry uncertainties. What troubles us is not the unknown—it is the delays in discovering critical answers. Why aren't the data we contribute as part of our care being used more effectively to shed light on treatment safety and efficacy?

I write this as a patient and advocate who has faced the consequences of inadequate evidence firsthand. Decades ago, I co-founded The Temporomandibular Joint Association (TMJA) to prevent others from enduring what I experienced: harm caused by treatments that lacked scientific evidence. The TMJA exists to demand better science for TMD and related conditions and to advocate for treatments that help rather than harm.

THE PROMISE OF REAL-WORLD EVIDENCE (RWE)

The 21st Century Cures Act was a mixed blessing. By accelerating the approval of treatments and medical devices, it promised faster access to life-saving innovations while addressing inefficiencies in identifying adverse effects post-approval. Yet for temporomandibular joint (TMJ) patients—and many others—that promise remains unfulfilled. The infrastructure needed to generate meaningful RWE has not been fully realized.

This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-Share Alike 4.0 License, which allows others to remix, transform, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

©2025 Published by Global Health and Education Projects, Inc.,USA.

Instead, we find ourselves grappling with the risks of an accelerated approval system. While the act shortened the time to market for treatments, it also reduced the number of patients required in clinical trials, leaving us with insufficient data to assess the long-term risks of these therapies. For TMJ treatments, this has led to devastating consequences – patients harmed by poorly tested devices and procedures.

BRIDGING THE GAP

The concept of RWE is not hypothetical. Coordinated Registry Networks (CRNs) already demonstrate their potential in specific medical areas. These networks bring together caregivers, researchers, and patients to collect and analyze high-quality data that not only tracks treatment safety and efficacy but also improves the quality of care. CRNs should be the gold standard for creating the evidence we need—but they remain underfunded and underutilized.

Over the past decade, billions of dollars have been invested in initiatives such as Sentinel and PCORnet, with mixed results. These approaches often lack the detailed data necessary for meaningful insights, like the unique device identifier. By contrast, CRNs provide a robust framework for generating actionable evidence, yet they have not received the level of investment required to expand their reach and impact.

A CALL TO ACTION

As we take stock of the progress made, it is clear that a strategic evaluation of RWE initiatives is overdue. Patients deserve evidence-based care informed by the most promising methodologies, such as CRNs. This requires bold leadership and a commitment to putting patients first – not only in rhetoric but also in action.

We commend the editors of this journal for dedicating this special issue to RWE. Their focus on bridging the gap between research and clinical practice aligns with what patients have been calling for science that translates into safer, more effective care.

IN MEMORIAM

This piece was drafted by Terrie Cowley and finalized after her passing by her close colleagues at The TMJA. Terrie was the co-founder and longtime president of The TMJA whose tireless advocacy was fueled by her personal experiences as a TMJ implant patient. Her efforts helped bring about transformative changes, including the establishment of the TMJ FDA Medical Device Epidemiology Network and the landmark 2020 report on TMD by the National Academies of Sciences, Engineering, and Medicine.

Terrie's greatest legacy, however, lies in the countless lives she touched. She listened. She fought. She gave voice to those in pain. As we continue her work, we honor her life of purpose and passion — a beacon of hope and determination for TMJ patients everywhere.

CONCLUSION AND IMPLICATIONS FOR TRANSLATION

Temporomandibular Disorders demand evidence-driven action. Patients are ready to contribute, yet the infrastructure to transform real-world experience into reliable evidence remains underdeveloped. Coordinated Registry Networks offer a clear path to safer, more effective care, but will only occur with sustained investment and a commitment to patient centeredness. It is time to turn data into insight, and insight into treatments that truly help—putting patients, not uncertainty, at the center of care.

Key Messages

(1) Real-world evidence is already proven useful: Coordinated Registry Networks (CRNs) are successfully collecting high-quality data in specific medical areas, demonstrating their potential to track treatment safety, efficacy, and improve care quality. (2) CRNs are underfunded and underutilized: Despite their effectiveness, CRNs are not receiving sufficient investment, limiting their ability to expand and fully realize their impact.

Acknowledgments: None.

COMPLIANCE WITH ETHICAL STANDARDS

Conflicts of Interest: The author declares no competing interests. **Financial Disclosure:** Not applicable. **Funding/Support:** Not applicable. **Ethics Approval:** Not applicable. **Declaration of Patient Consent:** Patient's consent not required as there are no patients in this study. **Use of Artificial Intelligence (AI)-Assisted Technology for Manuscript Preparation:** The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI. **Disclaimer:** None.

Special Collection

This article is published as part of the special collection on “Building the Real-World Evidence Infrastructure to Accelerate Innovation and Improve Outcomes in Healthcare.”

How to cite this article: Cowley T, Cowley AW. Real-world evidence: Why are we still waiting? *Int J Transl Med Res Public Health*. 2025;9:S7–8. doi: 10.25259/IJTMRP_18_2025