evidation

Understanding the neurological patient experience

Integrating real-world data sources to better measure and improve health in everyday life

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Introduction

For decades, real-world data (RWD) has supplemented findings from clinical trials. It's helped us understand drug utilization, effectiveness, and adverse events that may not have been apparent during initial asset testing and approval.

In some ways, however, traditional RWD isn't really from the real world — it's from the clinical world, mostly from claims and electronic health records. This is particularly true for neurological conditions, where so many significant everyday health experiences are invisible in current data sets.

How can we understand the lived experience of a migraine patient's day-to-day sleep issues, or a multiple sclerosis patient's mobility loss, to support better quality of life and health outcomes?

The next step in the evolution of RWD is major advancements in longitudinal RWD that's created, recorded, or gathered by or from individuals directly. Examples might include ePROs and surveys that hone in on experiences with specific conditions, treatments, health behaviors, and preferences or continuous objective measures from wearable devices and apps that provide a comprehensive, objective view of patients' daily life, activities, and disease progression.

This data can augment existing data sources to create a more complete picture of patient health and experiences, helping companies:

- Quantify the physical, physiological, functional, and psychological impacts of diseases and treatments in day-to-day life;
- See how treatments affect overall quality of life and activities of daily living;
- Understand barriers and experiences outside of the clinic;
- Identify and intervene based on granular, "real-world" segmentation and triggers; and
- Mitigate diagnosis, onboarding, and adherence issues

Traditional RWD alone falls short

Key neurologic treatment areas share critical challenges in understanding patients' experiences and engaging them in their care.

→ ***Incomplete picture of the patient experience and quality of life:***
Many people with neurological conditions go months between visits with providers, so claims and EHR data suffer from large gaps in the patient journey. These sources don't paint a complete picture of overall health, symptom and disease severity, or when and how patients are benefiting from their treatment. This can lead to lost opportunities to meaningfully engage patients at relevant moments in their disease progression, or needlessly cycling patients through multiple therapies before they achieve adequate management.

→ ***Subjective endpoints:***
Disease experiences in this space can be highly subjective, with clinically ambiguous patient-reported symptoms and no easily acquired biomarkers. It's hard to quantify how someone lives and copes with a condition and how these things change over time. Lab values and imaging don't qualify these experiences; amyloid scans alone, for example, aren't enough to assess the degree of Alzheimer's progression. This can lead to diagnostic errors and missed treatment opportunities.

→ ***Reliance on recall:***
Headache diaries are the gold standard for migraine symptom history, but they require months of accurate and time-intensive capture by patients in the midst of work, family, pain, disability, and other everyday hurdles. Many patients simply complete diaries from memory. Without reliable, objective symptom records, clinicians and researchers assess the impact of therapeutics without the concrete information they need.

Longitudinal patient-provided data paints a better picture

Off-the-shelf devices–such as computers, mobile devices, wearables, and other biosensors– can offer inexpensive, objective data that can quantify disease burden and add much-needed context to the longitudinal neurological patient journey.

More complete characterization of health, quality of life, and the lived experience

Multimodal sensor streams capture granular indicators of disease severity, progression, quality of life, treatment efficacy, and outcomes. They can quantify physical characteristics as well as psychosocial factors, which can help strengthen evidence generation of function measurement, scientific communication, and differentiation of data for stakeholder decision-making.

Direct patient data collection is non-invasive and isn't interrupted if patients move between providers or insurers. When mapped to traditional "real-world" clinical and claims data, it provides a more comprehensive view of people's lives. Clinicians can accelerate timelines for diagnosis and treatment when reviewing available data, and patients can have more productive conversations with their providers.

CASE STUDY

Exploring associations between passively collected tracker data and headache burden

Challenge

- The prevalence and burden of headache disorders in real-world settings is relatively unstudied
- The goal was to explore the associations between passively collected activity data, headache burden, and quality of life to elucidate new insights into headache self-management practices and treatment decisions, inform approaches for pain management, and identify individuals who might be eligible for clinical trials

Solution:

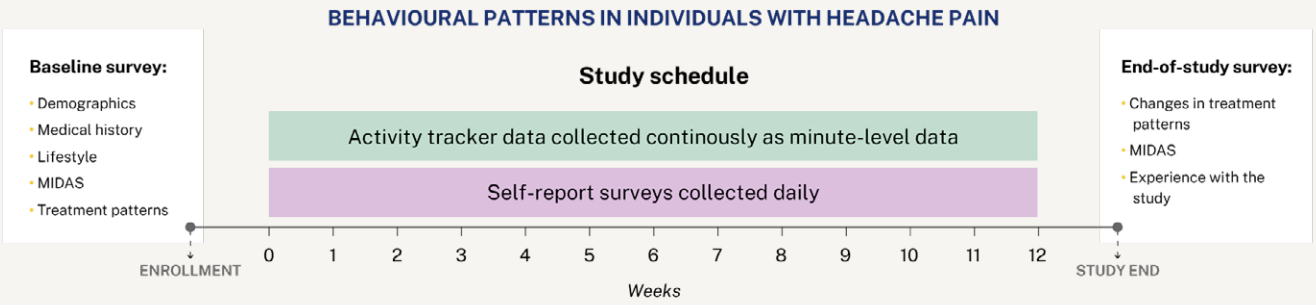
- Evidation enrolled 509 eligible US-based participants, all of whom were headache sufferers ≥ 18 years and self-reported experiencing 5-14 days with headache per month on average
- The team collected data from wearable activity tracking devices and daily short surveys over 12 weeks, allowing study participants to contribute in an unobtrusive and less burdensome manner
    - Compliance was high; on average, participants responded to 64 of 84 possible daily surveys and reported 9,646 headache days in total
    - 408 individuals met criteria for "dense" activity, defined as having no periods where they did not wear their Fitbit for 7 consecutive days or more
    - Participants contributed over 25,000 days of step and sleep data, demonstrating regular wear-time during the study
- Variables were analyzed using a series of mixed-effects models and stratified based on headache type
- Evidation used multiple linear and logistic regressions to analyze treatment preferences

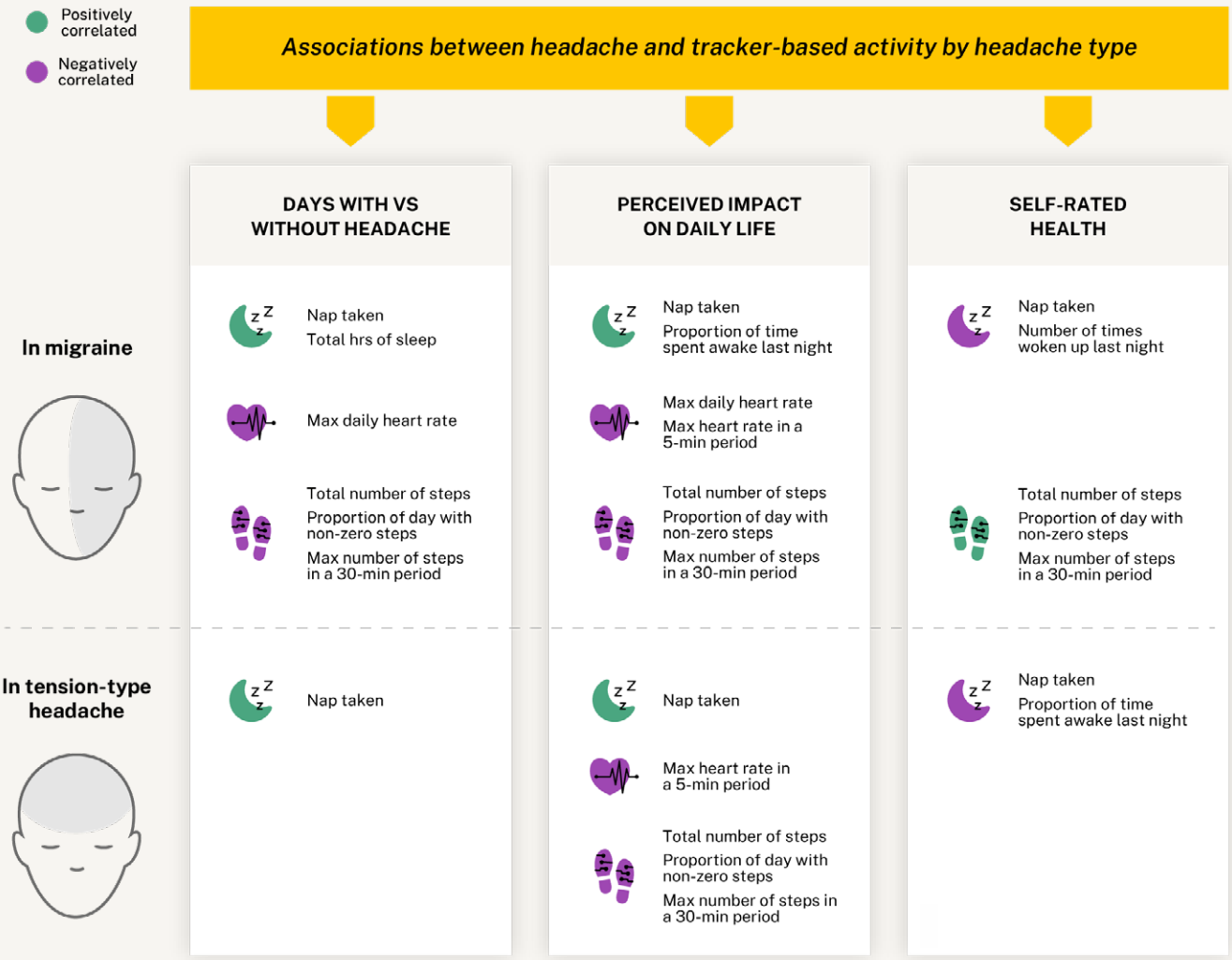
Results:

- Evidation found that days with headaches were typically associated with increased sleep, reduced physical activity, and lower maximum heart rate
- As headache-specific impact on quality of life increased, activity and maximum heart rate decreased while sleep increased
- Throughout the study, headache days with higher self-rated health were associated with less napping, higher step counts, and maximum heart rate (correlating with increased activity)

Key Takeaways:

- → Participants were able to contribute activity data passively, consistently, at scale, with low burden
- → The findings in this study provide preliminary evidence that activity trackers such as those found in wearable devices are useful tools when quantifying headache burden among individuals with frequent headaches in real-world settings
- → The data obtained in this study can be leveraged when developing new metrics that can be used in the future





Figures sourced from SpringerLink. **Read the full study here »**

Enhanced patient segmentation

Longitudinal RWD can help pharma segment and identify populations by neurologic phenotype, demographics, geography, and more at a scale that's impossible, or just financially impractical, in clinical trials. This data can help pharmaceutical developers and manufacturers track and characterize frequency, gather effectiveness data, and use that information to improve treatments and increase access to them.

With significantly more volume and diversity across the patient population, companies can utilize social determinants of health (SDoH) inputs, diversify research populations, and adopt more inclusive societal perspectives for decision-making.

Having more relevant measures in neurology also enables more personalized patient engagement and support to optimize adherence and, thus, the benefits of treatment. This can help find the right patient at the right time to make the right intervention, independent of their engagement with the traditional healthcare system.

CASE STUDY

Assessing the disease progression of patients living with multiple sclerosis through wearable data

Challenge:

- The value of digital devices for detecting changes in quality of life among people with MS is not clearly established, so there is a need for a proof of concept research
- The team aimed to use continuously collected consumer wearable data to differentiate patients with MS from those in a non-MS control group
- The intent was that this data could help determine mobility, which might serve as a proxy for disease state and progression in MS patients

Solution:

- Evidation used administrative claims data used to identify ~500 individuals living with MS and ~1500 living without
- The team computed daily summaries of both step and sleep data recorded by the minute via participant wearables

Results:

- Combining this data with claims and demographic data, experts could see notable differences between MS and non-MS individuals
- The team was able to identify flare-up events in patients with MS, paving the way for remote monitoring and management

Key Takeaways:

→ Digital devices have the potential to objectively and passively measure certain QoL metrics that can be used to evaluate the effectiveness of treatment approaches for people with MS

→ Digital devices have the potential to identify possible relapses and get people with MS to effective treatment earlier in the disease journey, producing better health outcomes and business outcomes

→ A wearable measure of function and flare-ups could help with running smaller clinical trials to determine efficacy, as well as more precision medicine in how patients track their function over time and with changing prescriptions as directed by their managing neurologist

How to generate high-quality longitudinal data

To leverage patient-provided data to more comprehensively characterize and segment patient populations—you first need to generate quality data. This is not as simple as it might sound. Patients often become disengaged over time, and data can become fragmented, making it hard to understand and measure their true lived experiences.

A solid long-term patient engagement strategy—including a plan to reach many people quickly, while also providing a great user experience—is crucial to overcoming these challenges.

For example, Evidation allows clients to both:

→ Achieve scale quickly

Why it matters

Generate data faster by swiftly recruiting large numbers of individuals

Considerations

- Leverage technology to create an easier and more convenient enrollment and research experience
- Employ precision recruitment
- Engage a research-ready community

→ Give patients a high-quality user experience

Why it matters

Generate data for longer periods by keeping people engaged over time

Considerations

- Use rewards and motivation
- Provide personalized and timely interactions—like. nudges, relevant health content, and predictive cards
- Offer an intuitive UI
- Maintain privacy, trust, and transparency
- Offer low-burden condition tracking

A more holistic view of your patients

Patients' lived experiences offer a more complete and insightful picture of their health. As we establish benchmarks, combine data sources, implement analytics, and explore the full potential of increasingly rich data, we'll build new ways of measuring the state and trajectory of disease.

Doing this aligns incentives across the health ecosystem: Healthcare professionals prescribe more personalized, effective treatments; individuals can be more proactive around their care and achieve better outcomes; and costs go down. Pharma can discover more meaningful, actionable patient insights to drive biomedical innovation and increase market value and differentiation.

If we trust patients and empower them with better tools to engage in and share about their health experiences, we not only get better data, but also place patients at the true center of the highest quality care.

To learn how Evidation engages individuals in order to characterize and quantify disease progression, treatment experience, and quality of life, **connect with a member of our commercial team.**