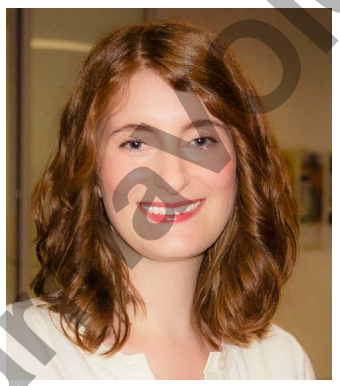
A Different Kind of Real-World Evidence: The Key Role That Patient-Provider Dialogue Research Can Play



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All roads in healthcare lead to and from the medical visit. Well, maybe not all roads, but nearly all. The medical visit is central to the overarching healthcare structure and it is driven by the dialogue between patient and provider.

The healthcare data and research landscape has been changing significantly over the past few years. Increasingly, real-world data (RWD) and real-world evidence (RWE) are being used to augment traditional clinical trial research for a variety of purposes. The Food and Drug Administration's evolving guidance on RWD and RWE has demonstrated growing support for their use and has bolstered focus and investment. Healthcare stakeholders, including pharmaceutical companies, payers, regulators, providers, and patients, are all increasingly looking to RWE to inform decision-making, support the development and approval of more treatment options, and demonstrate the true value of treatments.

One type of RWE that has been increasing is observational research. Before the rise of RWD and RWE, observational research had always been used to collect real-world data and produce real-world insights — this is the very definition. Observational research is continuing to be used in many of the same ways that other types of RWE are used. Increasingly, patient-provider dialogue observational research is being applied in RWE contexts. This research provides a real-world view into the critical medical visit dialogue.

What is Observational Research?

Observational research focuses on systematically observing, recording, and analyzing behavior and lived experiences in a natural setting. It can be qualitative, quantitative, or a mix of the two. Qualitative research is exploratory and descriptive — it approaches the study of human behavior by considering the participant's interpretation and assuming that reality is ever-changing and co-constructed. Quantitative research is designed to test a specific hypothesis and the data are collected numerically — it approaches the study of human behavior from the perspective that there are widespread social phenomena that are static and measurable. They are important complements to one another.

Observational research can also be either prospective or retrospective. Prospective research collects data for the purpose of the study. Retrospective research examines data that were collected in the past, usually originally for another purpose. Observational research also encompasses various types of research, including naturalistic studies, participant observation, case studies, and archival research, or content analysis. The most common type of observational research discussed in the context of RWE thus far has been retrospective quantitative content analysis of claims and electronic health record (EHR) data. While this type of RWE is growing and proving to be informative and beneficial, other types of observational research can also play an important role, including prospective qualitative approaches.

Why is Provider-Patient Dialogue Important, But Rarely Examined?

The patient-provider dialogue that occurs during the medical visit impacts everything else in the patient's healthcare journey. This dialogue determines:

- Whether the provider fully understands the patient's symptoms, functional and quality of life impacts, and concerns
- Whether the provider prescribes treatment, which one, and how he or she communicates that recommendation
- Whether the patient understands the purpose of the treatment and how it should be taken
- Whether the patient understands the goals of treatment and has appropriate expectations
- How satisfied the patient is with the provider and the treatment
- Ultimately, the patient's health outcomes

Clearly, such critical aspects of the healthcare journey have implications for all aspects of the healthcare industry and examining them can provide important insights. For example, lack of provider understanding of symptoms and functional and quality of life impacts can negatively affect diagnosis and prescribing, leading to patients not receiving treatment they need and poorer associated health outcomes. Also, weak provider recommendations, lack of patient understanding of the need for treatment and how it should be taken, lack of clear goal-setting, and patient misunderstanding of expectations can lead to patient nonpersistence and nonadherence, which can also lead to poorer associated health outcomes. When providers and patients do not communicate successfully during the medical visit and leave with disconnects, it can negatively affect not only patients and providers, but also pharmaceutical companies, manufacturers, payers, and other healthcare stakeholders.

Being at the heart of the healthcare journey and industry overall means that the medical visit dialogue is also rightfully sensitive and private, protected by Health Insurance Portability and Accountability Act (HIPAA) regulations, which makes access restricted.[1] Only specific types of research are appropriate.

How Can We Examine the Provider-Patient Dialogue?

Any research designed to examine provider-patient dialogue should follow HIPAA regulations and be approved by an Institutional Review Board (IRB), thus guaranteed to protect the welfare, rights, and privacy of the participants. IRB-approved research can

be published in peer-reviewed journals and shared in posters and presentations at medical conferences.

Communication is complicated. Dialogue is a nuanced collaborative activity, during which the participants co-create meaning and understanding. It is full of messages, the actual words spoken, but also meta-messages, the true meanings behind what is said.[2,3,4] Extracting insights from dialogue requires trained analysis of these dynamics — a keyword search of the transcript does not suffice.

Patient-provider dialogue research uses a theoretical framework called interactional sociolinguistics, which is grounded in anthropology, sociology, and linguistics. It is a form of observational research that enables the detailed examination of dialogue, often in the context of a specific cultural interaction, such as a medical visit. Due to the nature of the analysis, as with most other observational qualitative research approaches, the appropriate and validated sample size of this type of qualitative observational research is small compared with quantitative observational research. Just as "big data" has its place, so does "small data."[2, 3, 4]

A key aspect of the interactional sociolinguistic research framework is not only to observe and analyze dialogue, but also to interview the participants separately immediately after the interaction to measure what they intended, understood, and took away from the discussion. Often these interviews can illuminate areas of breakdown and miscommunication — gaps in understanding, issues not discussed, and misalignment on takeaways.[2, 3, 4] By immediately interviewing patients and providers, their thoughts before and during the visit and the nuances of the visit discussion are still top of mind. In addition, follow-up patient interviews weeks to months after the visit can reveal what they actually did, which is critical data when striving to understand adherence and outcomes.

Why Should Patient-Provider Dialogue Research be Used as RWE?

Patient-provider dialogue research can help to provide understanding and demonstrate the burden of disease that patients face, their unmet needs with the current standard of care, barriers to treatment prescription during the office visit, and misunderstandings and disconnects between providers and patients that often lead to underdiagnosis and suboptimal satisfaction and outcomes. This research can be used as RWE to support the need for, and value of, a product. It is currently most effective when used by pharmaceutical companies to communicate to payers and providers to support product value propositions and reimbursement decisions.

Patient-provider dialogue research aligns with the patient-centric approach that the healthcare industry has been moving toward. The office visit and the dialogue with the provider are central to the patient experience of healthcare. Successful patient-provider communication is critical to ensuring patients receive optimal care and related health outcomes. Employing patient-provider dialogue research as RWE and looking closely at these dialogues enables healthcare stakeholders to make more informed decisions, ultimately benefiting patients and others.

What Role Does Patient-Provider Dialogue Research Play Compared With Other Forms of RWE?

A primary concern with using clinical data that was originally collected for other purposes, such as EHR data and medical claims data, is data privacy. Health data are sensitive and, with common data breaches and increased ethical considerations, the healthcare industry is having to think critically about the ways that data are used. Regulations are catching up to the upsurge in available personal data with the European Union General Data Protection Regulation (GDPR) having gone into effect in May of 2018 and the California Consumer Privacy Act (CCCA) having been signed into law in June of 2018.[1] Data privacy and HIPAA compliance are built into IRB-approved observational patient-provider dialogue research. To receive IRB approval and eventually be published in peer-reviewed journals, the research must adhere to appropriate consenting processes and data protections.

Another concern with using clinical data that were collected for other purposes is that they were formatted and organized for those purposes. When used as RWE, this type of data must be reformatted and re-organized to fit this new purpose and there are inevitable gaps. Patient-provider dialogue data are rich and complex, but by using the validated interactional sociolinguistic research framework, it can be coded and analyzed systematically, producing high-quality research-level data that can be trusted.

From a patient perspective, claims data and EHR data are not fully representative of their authentic healthcare experiences — these sources of data represent the provider's point of view and the final prescribing decisions. Observation and analysis of patient-provider dialogue captures real patient experiences and post-visit interviews capture provider- and patient-provided perspectives. During these interviews, patients are able to convey the full experience of their condition, any functional and quality of life impacts, their understanding of their condition and treatment, and the next steps that they actually plan to take — much of which is often not fully discussed during visits. When compared with interviews with the providers, misunderstanding and misalignment become clear.

Conclusion

Quantitative observational data have their place, but patient-provider dialogue research is a worthwhile complement demonstrating nuances and datapoints that cannot otherwise be accessed. No other type of research is positioned to observe and analyze the critical visit dialogue and understand and demonstrate disconnects. Patient-provider dialogue research is fundamentally designed to protect participant privacy, produce high-quality and organized data, and explore authentic patient and provider experiences and perspectives. This research can be used as RWE to communicate the need for and value of a product, especially when supporting product value propositions and reimbursement decisions. PV

References:

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