Qualitative Methods Intersecting with Real-World Data Collection Methods

Advancing the Science of Patient Input in Medical Product R&D
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Disclosures: Gallup Organization; Adelphi Values; IQVia
Real-world patient symptom and treatment experiences

Why is this important?
Ubiquitous use of self-reports in science. Precision and reliability necessary to avoid being the “weakest link.”

How do we now collect information about patient experience?
Asking patients about symptoms and experiences over substantial periods of time.

Issues with retrospection:
Memory failure
Switch in type of memory
Cognitive heuristics (Peak-End, Duration Neglect)
Estimation techniques
Real-world patient symptom and treatment experiences

Development of Real-time and Near Real-time data collection strategies

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<td>Ecological Momentary Assessment (EMA)</td>
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<td>Experience Sampling Method (ESM)</td>
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Very brief descriptions:
- Environment (who, where, activity)
- Experiences (affect, stress, pain)
- Symptoms (study dependent).

- Data are collected in real-world environments, as subjects go about their lives. This is the “ecological” aspect of EMA.
- Assessments focus on subjects’ current state. This is the “momentary” aspect of EMA and aims to avoid the error and bias associated with retrospection.
- Moments are strategically selected for assessment.
- Patients complete multiple assessments over time, providing a picture of how their experiences and behavior varies over time and across situations.
Qualitative Methods to Enrich Assessments and for Hypothesis Generation

**Standard practice in development of self-report assessments**
Focus Group elicitation of core features of construct followed by Cognitive Interviewing to confirm respondent understanding and acceptability.

**Standard in Real-world assessments has not held to that standard**
There is no logical reason for this.

**Proposal: Qualitative Interviewing in the Real-World**
Switch from artificial testing to Real-time assessments.

**Benefits**
A deeper understanding of the experience people have in real-world; much may be unexpected.
Hypothesis generation based on new insights.

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