

Functional Medicine Research in Clinical Practice: A Call to Action for Practitioners

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Functional medicine-trained practitioners have conducted millions of patient care encounters worldwide. Many of these patients experience profound improvements in their health and wellbeing, and there is a growing evidence base that demonstrates the effectiveness of functional medicine.¹⁻⁶ However, the majority of these improvements in patient outcomes are not yet being systematically documented, analyzed, and disseminated.

While there is abundant evidence in support of individual modalities used by functional medicine practitioners, more outcomes data from research that evaluates the comprehensive care model serves to further influence policymakers, insurers, and governing agencies to promote change in the healthcare system. Furthermore, the increasing acceptance of practice-based real-world evidence^{7,8} presents a timely opportunity for practitioners to conduct research in their practices to further expand the functional medicine evidence base.

The Functional Medicine Research Component Checklist

To support the conduct of functional medicine research, The Institute for Functional Medicine (IFM) convened a panel of experts to develop and refine a practical checklist that describes the key components of functional medicine research. This checklist contains both essential and recommended care model characteristics that reflect their relative importance and feasibility in functional medicine research.

Functional Medicine Research in Clinical Practice: Barriers and Opportunities

A common barrier to practice-based research is the belief among many practitioners that they lack the time, resources, staffing, or training to contribute to research.

The Functional Medicine Research Component Checklist

Essential

- Reflects a system approach to health by observing or intervening upon imbalances across body systems that contribute to disturbances in function and/or disease
- Observes or intervenes upon antecedents, triggers, and mediators of disturbances in function and/or disease
- Features one or more modifiable lifestyle factors as an intervention, exposure, or stated inference related to the study findings
- Offers personalized approaches or employs methods to allow researchers or clinicians to infer how care may be personalized for patients

Recommended

- Acknowledges the importance of the therapeutic partnership
- Identifies/addresses mental, emotional, spiritual factors that influence health
- Raw data available via public repositories

This perspective is understandable, as clinicians have significant demands on their time and resources. However, research need not be all-consuming. Here are a few basic steps that practitioners can take to conduct functional medicine research in their practices.

First, obtaining signed informed consent for deidentified aggregation and analysis of outcomes data at new patient intake and among existing patients opens the doors for many research possibilities. This consent can be done electronically, and consent language can be simple and straightforward. Most patients are amenable—and often enthusiastic—about the prospect of contributing to the growth of the evidence base.

Second, collecting brief, validated assessments of physical and mental health (e.g., the 10-item PROMIS – Global Health questionnaire) at patient intake and at a regular cadence (every visit, every 6 months) allows for pooling patient data over time. More generally, although care is personalized to the patient, standardization of the intervals at which questionnaires, labs, and other outcomes data are collected broadens the measurable impact of the

care being provided. While the electronic health/medical record (EHR/EMR) data landscape is still in need of optimization for research purposes, standardizing outcomes collection in clinical practice settings can simplify future EHR/EMR data extracts and analysis.

Conducting randomized controlled trials of patient outcomes is challenging in clinical practice for a variety of reasons. However, there are numerous other study design types that can be feasibly and efficiently conducted by most practitioners for evaluating functional medicine care. These designs include case reports (aligning with the CARE guidelines^{10,11}), narrative reviews, and practice-based EHR/EMR data extractions.

While case reports and narrative reviews can be conducted independently by practitioners, forging partnerships with researchers for other types of study designs (e.g., EHR/EMR data extractions, serving as a site for an active clinical trial) can be a fruitful endeavor. Partnerships can help crystallize research ideas, provide methodological guidance, secure institutional review board (IRB) approvals (when applicable), and assist with peer-reviewed publication of research.

The manuscripts published in this issue are a testament to the feasibility of conducting functional medicine research in clinical practice. The projects were carried out by a diverse practitioner group, primarily without large grants or research staffs. Their work was done in a wide variety of clinical settings and represents a broad range of study designs. We hope these articles inspire and empower clinicians of all backgrounds to consider ways in which they may leverage their unique skills to conduct and publish functional medicine research. As these articles demonstrate, clinicians have the potential to meaningfully build the evidence base and support the widespread adoption of functional medicine.

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