From Innovation to Implementation: Bridging the System Gap in Healthcare Delivery

A Perspective from an ISCTM Workshop

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Abstract

Scientific innovation in healthcare has accelerated rapidly, particularly in central nervous system (CNS) disorders, biomarkers, and artificial intelligence. Yet the translation of these advances into meaningful improvements in patient outcomes remains inconsistent and delayed. This systems-level commentary, derived from a recent workshop of the International Society for CNS Clinical Trials and Methodology (ISCTM), examines why this translation gap persists and what changes are needed in healthcare delivery systems to close it. This gap does not reflect a failure of science, but a failure of systems. Drawing on discussions from a recent International Society for CNS Clinical Trials and Methodology (ISCTM) workshop, this perspective examines the structural, economic, and operational barriers that impede the adoption of innovation in real-world healthcare settings. Key challenges include misaligned incentives across stakeholders, inadequate attention to implementation and scalability, variability across healthcare ecosystems, and the persistent prioritization of treatment over prevention. We argue for a shift toward a systems-oriented framework for innovation—one that integrates payer, provider, and patient perspectives early in development; prioritizes usability and workflow integration; and aligns financial incentives with long-term outcomes. Without such changes, the growing pipeline of scientific advances risks failing to deliver on its promise to improve patient care. This perspective highlights implications for CNS clinicians, health system leaders, and payers who seek to improve the adoption, scalability, and sustainability of innovative diagnostics, therapeutics, and digital tools in routine care.

Introduction

Over the past decade, biomedical research has produced remarkable advances in diagnostics, therapeutics, and digital health technologies. In fields such as neurodegeneration and psychiatry, innovations including blood-based biomarkers, AI-enabled diagnostics, and novel therapeutics offer unprecedented opportunities to transform care. However, the impact of these advances on population health has been limited. In clinical neuroscience, including neurology and psychiatry, this translation gap is particularly consequential. CNS disorders frequently require long time horizons, multidisciplinary care, and integration of digital and biomarker tools, making the alignment

between innovation and health system capacity a central determinant of real-world impact.

This disconnect highlights a central challenge in modern healthcare: the translation gap between innovation and implementation. While the scientific enterprise has become increasingly efficient at generating new knowledge, healthcare systems remain constrained in their ability to absorb, scale, and sustain innovation.

The recent workshop convened by the International Society for CNS Clinical Trials and Methodology (ISCTM), an international scientific society focused on improving CNS clinical trials and methodology, examined this gap across the full continuum of drug and technology development, emphasizing that barriers to adoption arise less from deficiencies in evidence than from systemic misalignment across stakeholders, incentives, and operational realities.

Fragmentation Across the Innovation Pipeline

Fragmentation across the innovation pipeline means that products are often optimized for regulatory approval but remain misaligned with the needs and incentives of payers, clinicians, and health systems responsible for real-world adoption. Healthcare innovation unfolds across a multi-stage pipeline involving distinct stakeholders: researchers, industry sponsors, regulators, payers, clinicians, and patients. Each group operates under different incentives and decision frameworks. As a result, innovations are often optimized for success at one stage while remaining poorly suited for subsequent stages.

This fragmentation has been widely described in the literature as a core barrier to translation.[1,2] Clinical development programs are typically designed to satisfy regulatory requirements, focusing on internal validity and predefined endpoints, but may inadequately address payer concerns regarding value or clinician concerns regarding usability.[3] Consequently, products that achieve regulatory approval may still face significant barriers to reimbursement and adoption.

Incentives as the Primary Determinant of Adoption

A consistent theme across the workshop was that healthcare systems respond more strongly to financial and organizational incentives than to clinical evidence alone. Payment models, reimbursement policies, and financial risk structures exert a dominant influence on adoption decisions.

Fee-for-service reimbursement incentivizes procedures over prevention, while fragmented insurance structures discourage long-term investment in health outcomes.[4,5] These

dynamics create a structural bias against innovations that emphasize prevention, early detection, or longitudinal disease management.

Even when strong evidence exists, adoption may be limited if innovations increase short-term costs or lack reimbursement pathways.[6] As a result, economic context often outweighs clinical merit in determining uptake.

Redefining Evidence: From Validity to Usability

Traditional evidence hierarchies emphasize internal validity and reproducibility. However, real-world implementation requires a broader conception of evidence that includes scalability, feasibility, and context.

Implementation science has emphasized that effectiveness in controlled trials does not guarantee real-world impact.[7,8] From a real-world, practical perspective, interventions must demonstrate at a minimum a reasonable effect size to ensure health impact, a scope of services that allows for costing, scalability to reach the intended audience, and sustainability to ensure impact at scale over time[9] . In context of implementation reality, these would allow for:

- Scalability across diverse systems Integration into clinical workflows
- Cost-effectiveness under real-world constraints

This distinction between *efficacy* and *implementation* remains a critical gap in current development paradigms. Closing this gap will demand an advance in turning evidence of effectiveness into "decision-ready evidence" so care delivery leadership can move from theory into practice. The National Academies of Sciences, Engineering, and Medicine (NASEM) examined this concern and identified approaches to inform the National Institute of Heath and other funding agencies on strategies to close those gaps and included implementation science considerations in this effort.[10]

Heterogeneity of Healthcare Systems

Healthcare systems are not monolithic. In the United States, regional variation in healthcare delivery, outcomes, and utilization is well documented.[11, 12] These differences reflect variation in culture, policy, resource allocation, and institutional trust.

Such heterogeneity has important implications for innovation. Interventions that succeed in one context may fail in another due to differences in patient behavior, clinician practices, or system infrastructure.[13] Tailored implementation strategies are therefore essential.

The Clinician as Gatekeeper

Clinicians are central to the adoption of innovation but face increasing constraints, including administrative burden and workflow inefficiencies associated with electronic health records.[14,15]

For innovations to be adopted, they must: 1) Fit within existing workflows; 2) Reduce clinician burden; 3) Enhance decision-making without undermining autonomy. Trust is critical. Without clinician confidence and usability, even highly accurate tools will fail to gain traction.[16]

Economic Constraints and the Limits of Affordability

Rising healthcare costs present a major barrier to innovation adoption. High-cost therapies, including gene and cell therapies, challenge existing reimbursement models and raise questions about affordability and value.[17, 18] Payers must consider budget impact, time horizons, and population-level trade-offs. In fragmented systems, short-term financial incentives often conflict with long-term clinical benefits.[19]

Structural Bias Toward Treatment Over Prevention

Healthcare systems remain oriented towards treating disease rather than maintaining health. Preventive interventions are often underutilized despite strong evidence of long-term benefit.[20]This bias is particularly problematic in CNS disorders, where early intervention may be critical. However, delayed reimbursement and long-time horizons for benefit limit adoption of preventive strategies.

The Role of Social and System-Level Determinants

Health outcomes are strongly influenced by social determinants, including socioeconomic status, education, and access to care.[21] Interventions that address these factors can produce substantial improvements in outcomes, sometimes exceeding the impact of medical innovations alone. This highlights the importance of integrating healthcare innovation with broader system-level and community-based strategies.

Implications for Mental Health

Mental health care illustrates many of these challenges. Despite the availability of effective treatments, outcomes remain suboptimal due to fragmentation, access barriers, and inadequate system design.[22]

System-level interventions—such as integrated care models and measurement-based care—may yield greater improvements than new pharmacologic treatments alone.[23]

Toward a Systems-Oriented Framework for Innovation

Bridging the translation gap requires a shift toward a systems-oriented approach. Key elements include: 1) Integrate key stakeholders early in development (including payers, clinicians, and patients); 2) Align payment and organizational incentives with long-term clinical and functional outcomes; 3) Embed implementation science methods to generate decision-ready evidence for health system leaders; 4) Design innovations for scalability, usability, and workflow integration from the outset; 5) Tailor deployment strategies to the heterogeneity of health systems and patient populations; and 6) Incorporate social and system-level determinants of health into care models and innovation adoption decisions. For example, in Alzheimer's disease and related dementias, early integration of payers and health system leaders into development and implementation planning could accelerate adoption of blood-based biomarkers by aligning reimbursement, clinical workflow redesign, and population-level outcome metrics. Such a framework moves beyond product development to consider the full ecosystem in which innovation must operate.

Conclusion

The primary barriers to healthcare innovation are systemic rather than scientific; without redesigning incentives, decision-making frameworks, and implementation capacity, even the most promising CNS innovations will fail to achieve their potential in practice. Bridging the gap between discovery and real-world impact will require alignment across stakeholders, redefinition of evidence, and redesign of healthcare systems to support implementation. Our proposed systems-oriented framework emphasizes early stakeholder integration, aligned incentives, implementation science, scalability and usability, context-sensitive deployment, and attention to social and system-level determinants of health.

Without these changes, the expanding pipeline of biomedical innovation risks failing to translate into meaningful improvements in patient outcomes. For CNS clinicians, health system leaders, and payers, the imperative is to move beyond viewing innovation as a series of isolated products and instead co-design delivery systems that can reliably adopt, adapt, and sustain advances in ways that matter to patients and populations.

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