New Research Finds Key Groups Define Unmet Medical Need More Broadly Than Federal Clinical Standard

How do patients, caregivers, and healthcare stakeholders define unmet medical need compared to clinical standards?

WASHINGTON, DC, UNITED STATES, October 1, 2026 /EINPresswire.com/ -- Patients and family caregivers, along with a multi-stakeholder group, define unmet medical need more broadly than the clinical standard that federal drug policy relies on, according to two new studies from the National Pharmaceutical Council (NPC) and its partners.

Unmet medical need helps guide research and development priority in healthcare innovation, yet federal policy leans on a narrow definition, centered on clinical effectiveness and the availability of other treatments. The Centers for Medicare & Medicaid Services (CMS) weighs unmet medical need in the Inflation Reduction Act's Medicare Drug Price Negotiation Program, the Food and Drug Administration (FDA) builds it into the expedited pathways that speed some drugs to market, and payers weigh it in coverage decisions.

The two studies identified and ranked key dimensions of unmet medical need from distinct yet complementary perspectives. One study included 22 patients and family caregivers, while the other was made up of 17 stakeholders from research, industry, payer, policymaker, and patient-group backgrounds. Both groups ranked dimensions that were identified through a literature review of patient, caregiver, and societal perspectives, including those reflected in federal policy, clinical effectiveness, and the availability of other treatments. The review also identified broader domains: quality-of-life impacts, economic burden, treatment administration attributes, and health system functioning.

What mattered most differed by stakeholder group:

• Patients and family caregivers put health systems functioning first, followed by economic burden, quality of life, and availability of treatment alternatives. Traditional clinical effectiveness ranked fifth.

• The multi-stakeholder group put traditional clinical effectiveness first, followed by the availability of other treatments, quality of life, and economic burden.
Both groups ranked economic burden and quality of life as important dimensions that the

government's current definition omits.

"Patients, caregivers, and a broad group of experts all point in the same direction: unmet medical need reaches beyond whether a treatment works into how people access care, what it costs them, and how it affects their lives," said Jonathan D. Campbell, PhD, NPC Chief Science Officer and co-author of both studies.

The authors write that a broader, prioritized definition would help decisionmakers focus on where unmet needs are greatest. They call the two perspectives complementary and say future definitions of unmet need should draw on both. The authors note that this research is exploratory, and they call for additional efforts to best define and measure unmet need.

NPC managed both workshops with the University of Colorado Anschutz Medical Campus; the National Health Council co-managed the patient workshop.

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