DOI: 10.32385/rpmgf.v38i5.13609

Clinical trials in primary care: bridging the gap between evidence-based recommendations and clinical practice

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Randomized controlled trials (RCTs), especially in systematic reviews, are regarded as the gold standard for evaluating the effects of healthcare interventions. Several clinical trials aiming at translating results from clinical studies into everyday practice and health decision-making have informed clinical guidelines in all medical fields.[1] Besides research to develop evidence-based recommendations and policies, another step in translational research has been proposed including the research on implementing and disseminating evidence-based interventions in practice.[2]

Early reports[3-5] have summarized the difficulty of effective implementation and diffusion of proven healthcare interventions in primary care. Evidence-based innovations may fail to produce results when transferred to communities, largely because their implementation is untested, unsuitable, or incomplete.[6] Several epidemiologic approaches have contributed to the "implementation sciences" for assessing facilitators and barriers to the uptake and implementation of evidence-based recommendations. Limited generalizability of results in primary care settings may require analysis of biological, social, and environmental factors that impact implementation.[6] Researchers in primary care should consider that physical, behavioral, and social health are all intertwined, and thus achieving desirable outcomes may require complex interventions targeted not only directly to patients but also to structures and processes of care.

The number of published RCTs in primary care has been increasing over the last two decades; several of them have evaluated interventions on structures, and on processes of care as well as behavioral interventions that may facilitate the adoption of high-quality care.[7] Modifying structures, processes or behavior requires complex interventions that may act at multiple levels, incorporating features aiming both directly at patients and indirectly, through professionals and services, and vice versa. For example, primary care interventions might aim at improved training for clinicians to provide more patient-centered consultations; other interventions aimed at patients may require some change in the behavior or decisions of clinicians, and these changes in professional conduct, in turn, will also require some form of intervention, for example, new guidance, protocols or training. Interventions on primary care structures and processes may address inequalities in care delivery.[8-11] In contrast, behavioral interventions may change human behavior, support self-care programs, enhance long-term adherence, and improve healthcare indicators. Additionally, interventions on structures and processes may improve access to effective behavioral interventions limited by multiple barriers, including inadequate care delivery, workforce shortages, lack of outcome measurement, and payment methodologies that do not encourage high-value care.[12-13] The COVID-19 pandemic has raised new issues related to the delivery of care, including teleconsultation, missed

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care, virtual monitoring, and self-care training for consideration in future research planning.[14-17]

Complex interventions may incorporate main primary care characteristics, including the patient's first contact with the health care system, continuity, integration, and coordination of services.[18-19] Specific RCT designs including pragmatic, cluster or stepped-wedged trials may also be necessary to appropriately evaluate these interventions and ensure generalizability.[20] Building primary care research capacity for conducting RCTs to support this step of translational research in diverse regions could guide evidence-informed health policy; and thus, strengthen the role of primary care as a key partner in managing challenges in clinical practice.

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