Editorial

Implementation Research to Improve Cardiovascular Disease Management in India's Heterogeneous Primary Healthcare System

In India, cardiovascular diseases (CVDs) contribute to 28% of all deaths and 14% of overall health loss measured by disability-adjusted life years.[1] Compared to high-income countries, premature (<70 years) deaths due to CVDs are more common in India, which hampers India's economy.[2] The National Programme for Prevention and Control of Diabetes, CVD and Stroke has been developed to address the growing burden of CVDs. Piloted in 2006, the programme was scaled up nationally in 2014.[3] In 2018, the Government of India launched Ayushman Bharat Yojana, or 'Healthy India Programme'. The Ayushman Bharat Yojana adopts the continuum of care approach and comprises Pradhan Mantri Jan Arogya Yojana (PM-JAY) and Health and Wellness Centres (HWC).[4] The former—a major expansion of health insurance—received far more media and academic interest compared to the latter,[5,6] yet the latter represents a critical opportunity and challenge to deliver on the government's promise. Under the Ayushman Bharat Yojana, 150 000 existing subcentres and primary health centres will be transformed to HWCs to bring health closer to people by providing comprehensive primary healthcare, which includes scope for the diagnosis, prevention, treatment and control of CVDs.[7]

Whereas causal factors and treatments for CVDs are well established, implementation strategies to provide high-quality, accessible, affordable, timely and person-centred service related to CVDs have been less well developed. Strategies such as task sharing, mHealth and clinical decision support systems and governance, financing and social accountability mechanisms offer promise,[8–10] yet need contextualization, implementation, sustainment and scale-up and scale-out. Implementation research (IR) offers tools and framework to do so. We describe IR principles, dominant frameworks and examples as to how IR can help HWC deliver comprehensive CVD diagnosis, prevention, treatment and control in India's heterogeneous primary healthcare system.

Implementation research

IR has its origins in sociology, education and psychology among other disciplines. IR has been defined as 'the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services'.[11] IR aims not only to generate evidence but also to engage users and beneficiaries of interventions that are being implemented.

IR seeks to define and apply which implementation strategies work in which contexts and for which populations to close policy–knowledge–action gaps across different settings and groups, which is relevant to India's heterogeneous, state-based primary healthcare system. Hence, the research questions commonly asked are: What are the factors responsible for the implementation of the intervention? What is the context in which the intervention is being implemented? What are the barriers and enablers to implementation of the intervention? To answer these questions, quantitative and qualitative data are regularly gathered, analysed and synthesized. As the questions asked in IR differ from those of other areas of biomedical research, so too the outcomes, including acceptability, or the perception among implementation stakeholders that a

given treatment, service, practice or innovation is agreeable, palatable or satisfactory; adoption, or the intention, initial decision or action to try or employ an innovation or evidence-based practice; appropriateness, or perceived fit, relevance or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer or the perceived fit of the innovation to address a particular issue or problem; feasibility, or the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting; fidelity, or the degree to which an intervention was implemented as intended by the programme developers and sustainability, or the extent to which a newly implemented treatment is maintained or institutionalized within a service setting's ongoing, stable operations.[12] Another important characteristic of IR is the use of theories, frameworks and explanatory models to establish theoretical bases of the development, implementation and evaluation of interventions and implementation strategies. They provide insights into the mechanism by which implementation succeeds or fails.

IR, HWC and comprehensive CVD care

HWCs can play a transformative role in comprehensive CVD care through IR. Incorporation of IR in the early stages of HWC can strengthen and help to differentiate it from the existing model of primary care. We provide examples where interventions proven to be effective in other settings can be introduced via HWC, and IR can guide the corresponding implementation and evaluation strategies to improve CVD care.

A meta-analysis of trials (individual and cluster) published in 2019 has shown that task sharing to nurses for the management of blood pressure reduced the systolic blood pressure by 5.34 mmHg (95% CI 1.67–9.00) and diastolic blood pressure by 3.18 mmHg (95% CI 0.01–6.36).[8] In India, HWC nurses can screen for hypertension, refer to the primary health centre for management and impart community-based behavioural support for the control of hypertension. Lessons learnt from IR can contribute to the training of nurses in task shifting and its evaluation, assessment of barriers and enablers to task shifting, evaluation of intervention uptake and assessments of patient satisfaction. For example, using a cascade of care model, we can assess what proportion of patients referred for pharmacological management of hypertension receive and continue appropriate blood pressure-lowering therapies when referred by HWC-based nurses compared with usual, physician-based care delivery. Given the large numbers of beneficiaries who will access HWC, there is a potential to identify factors influencing good healthcare through integration of workflow with new technologies, such as machine learning and artificial technologies. While the HWCs are being designed, care should be taken to include data capture and parameters of interest that can be used for training and machine learning.

As a part of the HWC development, the Government of India plans to introduce a digital platform to connect accredited social health activists (ASHAs), auxiliary nurse-midwives (ANMs) and medical officers for effective management of non-communicable diseases, including CVDs.

IR findings can help in measuring and understanding the factors that promote or inhibit the incorporation of such interventions through models such as the Consolidated Framework for IR (CFIR; *cfir.org*). This framework is used in formative research development by defining and contextualizing the intervention, understanding the actors who are supposed to implement the intervention, the modifiable and non-modifiable inner (e.g. within HWC) and outer (e.g. beyond HWC) contexts in which the intervention exists and the process of the intervention's implementation. For the example of the digital platform, IR can help understand if the innovation makes sense to those who implement it and what modifications are needed; how well the actors are engaged in taking up and delivering the intervention; how the actors work together with the intervention in their HWC to determine its success or failure and what the actors think about its potential benefits and risks; the broader primary healthcare system context in which this intervention sits and the way in which HWCs and health workers operationalize the intervention by moving from theory to practice, including eventual long-term normalization.[13]

Second, IR can also help in de-implementing activities that have been shown to be ineffective or if better alternatives exist for current practices. For example, the accurate and reliable measurement of blood pressure is crucial for the diagnosis and management of hypertension. A difference of 5 mmHg of systolic blood pressure is estimated to

change the absolute prevalence of hypertension by 6% and can influence clinicians' diagnostic and treatment thresholds and targets. In India, blood pressure measurement is commonly done using manual mercury-based sphygmomanometers which require auscultation and are prone to measurement error and digit preference.[14] To accurately record blood pressure, manual sphygmomanometers can be de-implemented, and validated automatic blood pressure-measuring devices can be introduced.[14] The WHO HEARTS Package, which the Government of India is implementing through the India Hypertension Management Initiative in select states, advocates the use of digital blood pressure-measuring devices.[15] While this approach would require funds to replace the existing mercury-based sphygmomanometers (which have their own potential risks) and training in the use of automated blood pressure machines, this change can support non-physician health worker-based blood pressure screening. Similar to the example above, CFIR can be used for formative research to implement this approach via assessment of interventional characteristics, modifiable and non-modifiable inner and outer settings and actors involved in its implementation, whereas other models such as Reach, Effectiveness, Adoption, Implementation, and Maintenance can be used to assess implementation-specific outcomes such as:

- How many HWCs have automated blood pressure machines? (Reach)
- How many patients are being screened for hypertension with automated blood pressure machines? (Effectiveness)
- How many non-physician health workers are able to and are using these machines? (Adoption)
- Do HWC workers use the machines properly? How much time does it take for each patient? How much does it cost? (Implementation)
- What are the temporal trends in automated blood pressure machine use? (Maintenance).

Lastly, IR can contribute to the successful delivery and implementation of CVD interventions in assessing the context. India's heterogeneous, state-based primary healthcare system and society with different norms and practices preclude the 'one-size-fits-all' approach. To make interventions work, contextualization is critical, if not self-evident, and information derived from CFIR or other frameworks helps to tailor interventions using a structured approach to suit the local needs and to create generalizable knowledge about intervention implementation. For example, HWCs are required to educate the population on healthy diet to prevent CVD.[16] Dietary habits are different in different parts of India. Any intervention at the HWC aiming to promote a healthy diet has to account for local dietary practices and availability of seasonal fruits and vegetables in that particular geographical area.

Although we advocate the use of IR to strengthen CVD management, the discipline is relatively new and thus, some IR concepts and domains are not yet well developed for all contexts. For example, IR has been described to represent knowledge translation, knowledge management and change management among other concepts.[17,18] While theories, models and frameworks are crucial to understand and implement IR,[19] many of them have been developed and validated for its applicability in high-income country settings with limited use in low- and middle-income countries (LMIC) including India. Thus, researchers conducting IR or using IR principles to strengthen CVD management need to choose and contextualize these theories, models and frameworks to resource-constrained LMIC settings such as India.

We believe IR offers methods and tools to develop, implement and evaluate implementation strategies of new and existing interventions. Such strategies, implemented through HWCs, will help realize the goal of a Bharat that is truly Ayushman.

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REFERENCES

1 India State-Level Disease Burden Initiative CVD Collaborators. The changing patterns of cardiovascular diseases and their risk factors in the states of India: The global burden of disease study 1990–2016. *Lancet Glob Health* 2018;**6:**e1339–51.
2 Prabhakaran D, Singh K, Roth GA, Banerjee A, Pagidipati NJ, Huffman MD. Cardiovascular diseases in India compared with the United States. *J Am Coll Cardiol* 2018;**72:**79–95.
3 Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. *Operational Guidelines National Programme for Prevention and Control of Cancer. Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)*. New Delhi:Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India; 2010.
4 Ayushman Bharat Yojana. Available at *www.nhp.gov.in/ayushman-bharat-yojana_pg* (accessed on 21 Jun 2019).
5 Bahri C. Lessons from Rajasthan: Can Ayushman Bharat health scheme deliver results? Available at *www.business-standard.com/article/economy-policy/lessons-from-rajasthan-can-ayushman-bharat-health-scheme-deliver-results-118060600145_1.html* (accessed on 18 Jul 2019).
6 Das S, Jha AK. Getting coverage right for 500 million Indians. *N Engl J Med* 2019;**380:**2287–9.
7 Ayushman Bharat Health and Wellness Centre. Available at *https://ab-hwc.nhp.gov.in/* (accessed on 21 Jun 2019).
8 Anand TN, Joseph LM, Geetha AV, Prabhakaran D, Jeemon P. Task sharing with non-physician health-care workers for management of blood pressure in low-income and middle-income countries: A systematic review and meta-analysis. *Lancet Glob Health* 2019;**7:**e761–71.
9 Tian M, Ajay VS, Dunzhu D, Hameed SS, Li X, Liu Z, *et al*. A cluster-randomized, controlled trial of a simplified multifaceted management program for individuals at high cardiovascular risk (SimCard Trial) in rural Tibet, China, and Haryana, India. *Circulation* 2015;**132:**815–24.
10 Anchala R, Kaptoge S, Pant H, Di Angelantonio E, Franco OH, Prabhakaran D. Evaluation of effectiveness and cost-effectiveness of a clinical decision support system in managing hypertension in resource constrained primary health care settings: Results from a cluster randomized trial. *J Am Heart Assoc* 2015;**4:**e001213.
11 Eccles MP, Mittman BS. Welcome to implementation science. *Implement Sci* 2006;**1:**1.
12 Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, *et al*. Outcomes for implementation research: Conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;**38:** 65–76.
13 Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, *et al*. Normalisation process theory: A framework for developing, evaluating and implementing complex interventions. *BMC Med* 2010;**8:**63.
14 Padwal R, Campbell NRC, Schutte AE, Olsen MH, Delles C, Etyang A, *et al*. Optimizing observer performance of clinic blood pressure measurement: A position statement from the Lancet Commission on Hypertension Group. *J Hypertens* 2019;**37:**1737–45.
15 World Health Organization. HEARTS Technical Package for Cardiovascular Disease Management in Primary health Care: Access to Essential Medicines and Technology. Available at *https://apps.who.int/iris/bitstream/handle/10665/260420/WHO-NMH-NVI-18.3-eng.pdf?sequence=1* (accessed on 3 Nov 2019).
16 National Health Systems Resource Centre. *Ayushman Bharat: Comprehensive Primary Health Care through Health and Wellness Centers*. New Delhi:National Health Systems Resource Centre; 2018.
17 National Cancer Institute, National Institutes of Health. About Implementation Science. Available at *https://cancercontrol.cancer.gov/IS/about.html* (accessed on 5 Nov 2019).
18 Canadian Institutes of Health Research. Knowledge Translation. Available at *www.cihr-irsc.gc.ca/e/29418.html#2* (accessed on 5 Nov 2019).
19 Nilsen P. Making sense of implementation theories, models and frameworks. *Implement Sci* 2015;**10:**53.

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