Controlling cardiovascular diseases in low and middle income countries by placing proof in pragmatism

Mayowa Owolabi,1,2 Jaime J Miranda,3,4 Joseph Yaria,1 Bruce Ovbiagele5

ABSTRACT

Low and middle income countries (LMICs) bear a huge, disproportionate and growing burden of cardiovascular disease (CVD) which constitutes a threat to development. Efforts to tackle the global burden of CVD must therefore emphasise effective control in LMICs by addressing the challenge of scarce resources and lack of pragmatic guidelines for CVD prevention, treatment and rehabilitation. To address these gaps, in this analysis article, we present an implementation cycle for developing, contextualising, communicating and evaluating CVD recommendations for LMICs. This includes a translatability scale to rank the potential ease of implementing recommendations, prescriptions for engaging stakeholders in implementing the recommendations (stakeholders such as providers and physicians, patients and the populace, policymakers and payers) and strategies for enhancing feedback. This approach can help LMICs combat CVD despite limited resources, and can stimulate new implementation science hypotheses, research, evidence and impact.

INTRODUCTION

The world is facing an enormous health disparity.1,2 The largest burden of non-communicable diseases especially cardiovascular diseases (CVDs), which constitute the leading cause of death and disability in the world (accounting for 60% of global deaths), is borne by low and middle income countries (LMICs).1,2 Unlike high income countries (HICs), LMICs lack the resources and pragmatic solutions to tackle this crippling yet increasing burden.1,2 In this article, we proffer a novel implementation cycle for identifying and implementing effective solutions to combat the rising CVD burden in the low-resource settings of LMICs, by placing proof in pragmatism.

THE GROWING GLOBAL DISPARITY IN CARDIOVASCULAR HEALTH

Any attempt to successfully tackle the global burden of CVD must emphasise its effective control in LMICs where it is a threat to development.1,2 However, although up to 90% of the worldwide CVD burden is borne by LMICs, they have only about 10% of the research capacity and healthcare resources necessary to investigate and identify sustainable solutions to address this escalating challenge.1–4

Moreover, proven therapies and strategies for controlling CVD developed in HICs may not necessarily be pragmatic for LMICs if not adapted.9 Owing to the relative paucity of locally conducted research, care...
providers in LMICs seeking to practice evidence-based medicine often attempt to directly incorporate available practice guidelines imported from HICs, even though the settings, patients and resources are vastly different (tables 1–3). In particular, geopolitical and socioeconomic problems in most LMICs present barriers to optimal CVD control. These include low population health literacy, limited health budgets, corruption, uncoordinated health systems, unstable political climate, faulty policies, negative influence of certain food industries and tobacco companies, lack of appropriate infrastructure, deficient pharmaceutical supply chains, predominant out-of-pocket health expenditures and barely existent health insurance systems.

Therefore, despite existing high-level evidence-based guidelines from HICs and clear evidence of a declining CVD burden in HICs, the CVD burden continues to escalate among LMICs. The ongoing ‘parallel CVD universes’ is akin to the situation in global polio prevention efforts where despite the discovery of the polio vaccine over half a century ago, new cases are still occurring in LMICs. Within the socioeconomic reality in LMICs, contextually appropriate recommendations for CVD control need to be developed.

Ideally, new direct evidence about the effectiveness of CVD interventions in LMICs settings should be generated, but currently, LMICs do not have the wherewithal to support CVD implementation science initiatives. Also, there are insufficient resources from HICs to support CVD research in LMICs in a widespread and long-term manner. Since the aforementioned potential strategies to ameliorate the CVD burden in LMICs will be either partial or long term, and presently lives are being lost and futures blighted, intervening action is warranted in the mean time.

Systematic approaches are urgently needed to translate the existing high-level evidence obtained in HICs into pragmatic strategies to reduce the escalating burden of CVD in LMICs, while gradually creating an implementation pipeline to stimulate, absorb, process, and disseminate new direct evidence as they accrue from LMICs in future. This should include a new approach to the content, packaging and delivery of evidence-based recommendations to make them more accessible, contextual, and actionable, across the CVD-care continuum, involving all stakeholders, while avoiding disease siloes, in LMICs where the burden is heaviest (figure 1).

### TRANSLATING THE CONTENT OF EVIDENCE-BASED RECOMMENDATIONS

First, there is a need to unravel the major gaps and needs for interventions to control CVD in LMICs along the entire cardiovascular cascade from ideal cardiovascular health, through emergence of CVD risk factors, to symptomatic CVD culminating in disability and death. This should cover the entire intervention spectrum as proposed in the cardiovascular disease quadrangle (epidemiological surveillance and research networks including establishment of research agenda and priorities; primordial, primary and secondary prevention across

![Table 1](image-url)
Table 2  Action should involve all stakeholders (sections of ‘the bridge’)

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Examples of actions and roles required to control CVD</th>
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<tbody>
<tr>
<td>Patients</td>
<td>Evidence-based cardiovascular health information/tips, educational materials, self-efficacy tools to be made available through novel multiple friendly channels to patients to enable them take, seek and evaluate appropriate preventive, therapeutic and restorative actions.</td>
</tr>
<tr>
<td>Providers</td>
<td>High-level translatable customised recommendations to be made available/accessible to clinicians, physicians, pharmacists and other medical and paramedical personnel in LMICs using multipronged novel-friendly channels. Development of task-redistribution approaches. Training and capacity building. This will enable them to be aware of and implement such recommendations in eligible patients.</td>
</tr>
<tr>
<td>Populace</td>
<td>Using several novel channels, media, forums and community resources to engage the entire general populace across the lifespan about the burden, prevention and other interventions for the entire spectrum of CVDs (Cardiovascular Cascade) from ideal cardiovascular health to cardiovascular death. This includes population level screening for CVD and CVD risk factors and awareness campaigns in communities, schools, workplaces, places of worship, workspace, etc. This will enable them take, seek and evaluate appropriate preventive, therapeutic and restorative actions.</td>
</tr>
<tr>
<td>Policymakers</td>
<td>Collection and synthesis of the best available global and local evidence to produce evidence briefs for policy as the primary input into structured deliberate dialogues with the policymakers. Engagement of all layers/grades of policymakers using novel channels. This will enable them to provide relevant infrastructure, medications, facilities and equipment, develop evidence-based translatable policies and performance indicators and formulate policy networks and peer-review mechanisms for policy implementation.</td>
</tr>
<tr>
<td>Payers</td>
<td>Engagement of payers to support the implementation of high-level recommendations with relevant resources. Discounts, subsidies, supplementation, local manufacture of generic products and donations could improve access to medications and devices.</td>
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</table>
| Partners     | No single organisation can combat the CVD epidemic alone. It is inevitable to establish and nurture a broad-based synergistic system of collaborations among the implementation partners including:  
  A. Researchers and research institutions to identify and resolve research gaps, set research agenda/priorities, along the entire cardiovascular cascade and cardiovascular quadrangle (epidemiological surveillance; primordial/primary/secondary prevention; acute/hyperacute intervention; and rehabilitation/reintegration).  
  B. Relevant national, regional and global professional bodies to engage and learn from each other and interact with other implementation partners and stakeholders to develop and implement best interventions to combat CVDs in LMICs eg, World Hypertension League, International Society of Hypertension, Nigerian Stroke Society, World Federation for Neurorehabilitation, National Medical Associations, American Heart Association, European Academy of Neurology, American Society of Hypertension, European Hypertension Society, American Academy of Neurology, International Academy Medical Panel, NICE, World Stroke Organization, World Federation of Neurology, Pan-African Society of Cardiology, Indian Stroke Association, Chinese Society of Neurology, H3Africa CVD Consortium, societies relevant for ethical, legal social and policy-related issues as well as agricultural/pharmaceutical sector with influence on availability of healthy food and cost-effective drugs, Global Burden of Disease expert group, the Non Communicable Diseases Risk factor Collaboration (NCD-RiSC) consortium, etc.  
  C. Relevant governmental and intergovernmental agencies (to set, facilitate, implement and evaluate a global agenda for the control of CVD in LMICs) eg, Federal and State Ministries of Health, WHO, African Union, NEPAD, European Union, European Commission, World Health Summit, G7, G20, World Bank, African Development Bank, National Health Research Councils, United Nations, National Institute of Health (USA), NHLBI, Medical Research Councils (UK, South Africa, etc), CIHR, ICMR, CAMS, INCNMSZ, NMHC, Welcome Trust, and other funding agencies.  
  D. Relevant non-governmental organisations and private sector eg, mobile phone companies which may offer free or subsidised text messaging platforms, film industries which may support applied theatre techniques (Bollywood, Nollywood, Hollywood, etc), philanthropic organisations (eg, Bill Gates Foundation, Dangote Foundation, etc), pharmaceutical and medical supplies companies may provide medications and materials at lower costs for LMICs as part of their social responsibility, print and electronic media houses: to support health awareness programmes in LMICs.  
  E. Advocates and ambassadors: Volunteering individuals and groups, opinion leaders, professional, faith-based, community and political leaders who are affected by CVD or whose close relations are affected by CVD to advocate for control of CVDs. |
Next, CVD practice guidelines for LMICs could be developed (or enhanced where already available) using solutions from the corresponding successful HIC guidelines which can be adapted to LMICs healthcare peculiarities. The focus should strictly be on high-level recommendations (ie, class I or III evidence with level A recommendations only) for the selected CVD entities. However, to develop such sustainable solutions, the multilevel barriers and facilitators of implementing CVD guidelines in LMICs need to be fully understood. Examples of such barriers include socioeconomic and ecological conditions as well as societal upheavals which influenced the sustainment of interventions in sub-Saharan Africa. Thus, gaps and barriers in the implementation pipeline including lack of relevant facilities, devices, medications and personnel should be taken into account while adapting the high-level content.

The complexity and nature of these barriers vary for different interventions. While some interventions can be implemented at home by the individual without the need for sophisticated equipment, highly skilled medical personnel, advanced medical infrastructures or new legislations, others would require all of these for implementation. Therefore, in addition to ranking solutions according to classes of evidence and levels of recommendation only for the selected CVD entities, new guidelines could be developed (or enhanced where already available) using solutions from the corresponding successful HIC guidelines as well as low-socioeconomic conditions that are neither limited by cost nor personnel. In most cases they can be implemented by individuals on their own with little or no need for highly skilled personnel and/or expensive appliances (eg, dietary activity,14 dietary salt reduction,15 healthy dietary choices).

The proposed scale could be modified to make it more reproducible once adopted and in use as practical issues arise regarding the nature and relative complexities of barriers that need to be navigated for successful implementation. Therefore, in addition to linking solutions according to clinical usefulness, it is crucial to grade them in descending order of translatable (figure 1, point (D)). A translated summary for grading solutions according to the nature and relative complexity of barriers that need to be navigated for successful implementation is proposed below. The proposed scale could be modified and use as practical issues arise regarding its application.

The proposed scale could be modified in future studies to include grading solutions according to their ability to adapt to local contexts (eg, to facilitate successful implementation of CVD guidelines in LMICs). This would allow for the development of solutions that are specifically tailored to the unique needs and challenges of LMICs. In conclusion, the proposed grading scale could be used as a tool to assess the feasibility and acceptability of solutions for CVD guideline implementation in LMICs. This could help to identify gaps and barriers in the implementation pipeline, and inform the development of solutions that are more likely to be successful in LMICs.
Table 3 Evidence for the missing links in existing cardiovascular diseases guidelines for low and middle income countries: the diabetes mellitus scenario from three continents

<table>
<thead>
<tr>
<th>Country/region</th>
<th>Malaysia/Asia</th>
<th>Brazil/South America</th>
<th>South Africa/Africa</th>
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<tbody>
<tr>
<td><strong>Publication details</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td>2015</td>
<td>2010</td>
<td>2012</td>
</tr>
<tr>
<td><strong>Title</strong></td>
<td>Management of type 2 diabetes mellitus (5th edition)6</td>
<td>Algorithm for the treatment of type 2 diabetes: a position statement of Brazilian Diabetes Society5</td>
<td>The 2012 SEMDSA guideline for the management of type 2 diabetes (revised)7</td>
</tr>
<tr>
<td><strong>Authors</strong></td>
<td>Ministry of Health, Malaysia</td>
<td>Lerario AC, et al</td>
<td>SEMDSA</td>
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<tr>
<td><strong>Basis of recommendation</strong></td>
<td>Modified from Scottish Intercollegiate guidelines network, systematic reviews, meta-analysis, local practice considerations</td>
<td>International literature, ADA/EASD algorithm. Joslin Diabetes Center</td>
<td>Update literature and the Department of Health’s draft type 2 diabetes guideline document.</td>
</tr>
<tr>
<td><strong>Specialties of the members of task force</strong></td>
<td>Endocrinologists Family medicine specialists General physicians Paediatric endocrinologists Public health physicians Dieticians</td>
<td>NS</td>
<td>Endocrinologists Family Practitioners Diabetes Educators Department of Health representatives. Medical Council representatives</td>
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<tr>
<td><strong>Methods in detail</strong></td>
<td>Members of the task force were assigned topics. Articles retrieved were graded. Draft guideline was posted on the Malaysian Endocrine and Metabolic Society, Ministry of Health Malaysia websites for comment and feedback. Guideline presented to the Technical Advisory Committee and the Health Technology Assessment and Clinical Practice Guidelines Council, Ministry of Health for review and approval.</td>
<td>Brazilian Diabetes Society obtained opinions of a panel of renowned Brazilian specialist about recommendations and controversial arguments on the treatment of T2DM in international literature. Arguments were presented to the panel with each member scoring each argument on a Likert scale.</td>
<td>Broad topic of management was divided into smaller sections and allocated to experts to lead. Information on each section was presented to the general committee and amendments and additions suggested best on ‘best practice’.</td>
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Clinical issues addressed (components of the cardiovascular quadrangle)

<table>
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<tr>
<th></th>
<th>Primordial prevention</th>
<th>Pre-diabetes</th>
<th>Age-specific treatment</th>
<th>Nutrition</th>
<th>Exercise</th>
<th>Acute care/emergencies</th>
<th>Conventional care</th>
<th>Rehabilitation</th>
<th>Physicians</th>
<th>Nurses</th>
<th>Primary caregivers</th>
<th>Pharmacist</th>
<th>Dieticians</th>
<th>Policymakers</th>
<th>Payers</th>
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<td>Malaysia/Asia</td>
<td>No</td>
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Continued
While determining translatability, ethical, legal, sociocultural and economic (ELSE) factors should be considered (figure 1, point D) in addition to other barriers and facilitators. Just telling an individual patient to reduce alcohol use may be difficult although cheap. However, if the guidelines consider the sociocultural uniqueness of the country, then allocation can be made for family or religious input. Use of translatability weighting gives every healthcare provider a recommendation to work with irrespective of their cadre. There is nothing to be gained in forcing the latest thrombolytic therapy down the throats of a health extension worker in an African village when he/she is never going to be able to get it done. Why not just ensure that they at least follow proven Ta practices for CVD prevention and treatment?

However, while Ta preventive interventions such as increasing physical activity and modifying diet are highly cost-effective ultimately, implementing them at scale in a population may require significant expenditure initially. Their implementation may also be hindered by difficulty in changing entrenched behaviours at the individual and population levels particularly as they may require changing norms to prevent an invisible problem without immediately obvious benefits. For instance, individuals may not immediately realise that unhealthy diet and sedentary lifestyle can lead to atherosclerosis, stroke and premature death. So the challenge is in making the consequences of sedentary lifestyle and unhealthy diet obvious and communicating the effectiveness and basis of the required change at the population and personal level. This may include funding of mass educational programmes needed to motivate change and provision of an enabling environment to make the change possible and sustainable. Social capital can be provided through family and social activities such as ‘walk for life’ exercise programmes integrated into the routine activities by community, professional and religious groups.

Nevertheless, adopting the translatability scale can encourage the discovery, development, prioritisation and adoption of highly effective adaptable Ta recommendations which can perhaps be more easily implemented by all stakeholders in LMICs. It can also promote implementation science research for the modification of barriers and facilitators for the translation of Ta recommendations in order to elevate them towards Ta status.

The implementation of complex interventions in primary care is influenced by the evidence of benefit, ease of use and adaptation to local circumstances. Identifying and overcoming the causes of the evidence-to-practice gap and improving the translatability and ‘fit’ between intervention and context is critical in determining the success of implementation. The current scenario presents a unique opportunity to develop and implement Ta solutions and recommendations in LMICs. In addition, implementing such high level Ta recommendations in LMICs can provide insights for implementation in HICs. These considerations can inform the development of pragmatically weighted recommendations in the form of guidelines, practice points, statements, health tips and messages on CVD which are packaged and tailored to all specific audiences (tables 1 and 2).

Examining existing LMICs CVD guidelines through the lens of the implementation cycle reveals gaps in their development and content (figure 1, points (A–D)). This is illustrated by three type 2 diabetes mellitus
guidelines from LMICs in three continents\textsuperscript{5–7} (table 3). Apart from weaknesses in the content (such as lack of adequate and systematic considerations of translatability, ethical, legal, socioeconomic implications), appropriate user-friendly dissemination channels to target audiences were not clearly articulated.\textsuperscript{5–7}

**ENGAGING STAKEHOLDERS IN THE DELIVERY OF RECOMMENDATIONS**

Bulky consensus guidelines published by many professional bodies in academic journals to increase healthcare providers’ awareness of evidence-based approaches to disease management have often neither percolated down to the stakeholders nor produced the desired results.\textsuperscript{16} Dissemination of high-level CVD recommendations in LMICs, therefore, must be transformed and combined with effective implementation strategies to drastically improve the knowledge, attitude, behaviour and practice of all stakeholders and foster an enabling implementation environment so as to produce and sustain the desired effects (tables 1 and 2).

Hitherto, attention has been focused solely on ‘the car’ (the evidence-based recommendation) to the exclusion of ‘the bridge’ (the stakeholders) over which the car must ply in order to deliver the care and desired outcomes (figure 1 and table 1).\textsuperscript{17} For example, the timely delivery of thrombolytic therapy to eligible patients who suffered a stroke\textsuperscript{17} requires the coordinated actions of all stakeholders including the patient, caregiver and all other players in the health sector.\textsuperscript{19} Therefore, in LMICs, there is a need for contextualisation (targeted packaging) of solutions and their dissemination through novel cost-effective multidirectional interactive channels to mobilise every stakeholder so as to foster ownership by all. This is in line with the recognition of community ownership and mobilisation as crucial
facilitators for intervention sustainability, both early on and after intervention implementation by many of the 41 studies (1996–2015) in a systematic review of empirical literature to explore how health interventions implemented in sub-Saharan Africa are sustained. These findings further support the recommendation of contextualisation and targeted packaging of solutions to all relevant specific audiences in the implementation cycle. Considerations for contextualisation should include factors related to each of the 6Ps (tables 1 and 2 and figure 1) including external contextual factors (policies, incentivisation structures, dominant paradigms, stakeholders’ buy-in, infrastructure and advances in technology), organisation-related factors (culture, available resources, integration with existing processes, relationships, skill mix and staff involvement) and individual professional factors (professional role, underlying philosophy of care and competencies).

Apart from gaps in contextualisation, the communication of solutions to targeted audiences through appropriate channels is often deficient (figure 1, point (F)). For instance, in a survey of 485 UK-based principal investigators of publicly funded applied and public health research, less than one-third stated that they would produce key messages for specific audiences. This is despite the fact that most respondents indicated that part of their dissemination plan involved targeting specific audiences (such as policymakers, service managers or general practitioners). Although researchers recognise the importance of disseminating the findings of their work, they are focused on academic publications and the few who apply a range of dissemination channels do so in an uncoordinated fashion.

This critical communication gap must be addressed comprehensively. Therefore, although it is not clear which channels work best, we propose communication cycles and circles to disseminate targeted key messages through multiple channels including social media, text messaging platforms, mobile phone apps, applied theatre arts, websites, mobile health platforms, electronic media, print media, dedicated forums and monitoring software/dashboards. This will enable researchers to interactively and continuously engage with all stakeholders; such as providers (personnel–clinicians, healthcare workers), policymakers, patients, populace (communities), partners and payers (table 2 and figure 1, points (E and F)). The right combinations of channels can be selected based on the preferences of the target audiences and accruing evidence.

**ENHANCING FEEDBACK BY HARMONISING OUTCOME MEASURES**

The effectiveness of the entire implementation process and dissemination channels should be evaluated using appropriate measures. Although it is known that implementation will greatly benefit from easy-to-apply, harmonised and rigorous outcome measures; reviews suggest that less than half of the existing measures are psychometrically validated (ie, in many cases, no data exists on whether the measure assesses the construct it is intended to address). Other challenges include the difficulties in applying such measures in routine clinical practice settings, and the dearth of measures available for certain implementation constructs (eg, context and adaptation). Furthermore, the use of different outcome measures by similar studies prevents the integration of results across such studies.

It is therefore crucial for implementation partners (table 2 and figure 1) to develop and use *simple and effective harmonised outcome measures and performance indicators* to monitor and evaluate implementation progress along the four axes of the cardiovascular quadrangle. For example, reducing the burden of stroke will require the monitoring of stroke surveillance, prevention, acute care and rehabilitation services. Enhancing the quality of such feedback will facilitate the identification of evidence gaps and implementation barriers, which can in turn lead to new research studies (figure 1, points (A, B and G) and yield better evidence and recommendations.

This will potentially fast-track integrated knowledge translation driven by collaboration between researchers and decision-makers. Patients and service leaders can help researchers to clarify goals, gather new evidence in real-life complex systems, and identify appropriate approaches for conducting and evaluating planned changes. Such evaluations may be formative, using findings to optimise implementation, or summative, producing evidence of ultimate impact or both. In any case, careful thought is needed to protect the integrity of evaluations and feedback.

**CONCLUSION**

Practice guidelines are developed based on the strength of available evidence. However, the reality is that most of the strong evidence stem from clinical trials which usually test ‘one thing at a time’, and not necessarily how complex systems operate. Ironically, although the recommendations are often published in high-impact visible journals, they are often poorly contextualised and communicated and so do not percolate down to key stakeholders, and their implementation remains a challenge, particularly in LMICs. We therefore propose an *implementation cycle* which addresses hitherto missing links in CVD solutions. It includes strategies for generating new evidence in real-life complex ecosystems and implementation environment, and processes for content development, contextualisation, communication and feedback (figure 1). This pathway can incrementally stimulate, monitor, absorb and process the accruing evidence from researchers and consortia examining CVDs in LMICs while motivating all stakeholders and creating enabling environment for the implementation of existing evidence-based solutions. Holistic deployment of this cycle, placing proof in pragmatism, can
revolutionise our capacity to tame the burden of CVDs in LMICs despite limited resources.

Handling editor Seye Abimbola
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Contributors MO drafted the manuscript. All authors gave substantial contributions to the conception of the paper and revised it critically for important intellectual content. All authors approved the final version of the paper for publication. MO is the guarantor.

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