



Advancement of the implementation of evidence-based therapies for cardiovascular-kidney-metabolic conditions: A multi-stakeholder perspective

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ABSTRACT Cardiovascular disease remains the leading cause of mortality and healthcare expenditures in the United States. It is also a major contributor to premature mortality, years lived with disability, and rising healthcare costs around the world. Despite the availability of proven therapies and interventions that could vastly decrease the burden of cardiovascular disease and cardiometabolic conditions, their implementation is poor, with generally less than half of patients being treated with the most effective therapies. Implementation science offers promise in bridging this gap and mitigating disparities. However, even though small studies have shown that there are effective methods to improve the implementation of evidence-based therapies, these methods have not been scaled to make an impact at the level of health systems or nationally. A coordinated, multi-stakeholder approach is essential to identify barriers to implementation on a broad scale and, more critically, to develop and deploy practical solutions. The Duke Clinical Research Institute conducted an Implementation Summit entitled “Scalability, Spread, and Sustainability” to explore strategies for advancing the uptake of evidence-based interventions for cardiometabolic diseases in healthcare in the United States. This manuscript presents the participants’ multi-stakeholder perspective on the steps necessary to improve the implementation of evidence-based therapies in cardiometabolic disease. Key recommendations include focused efforts on evidence generation around broad implementation strategies, dissemination of the evidence generated, uptake of evidence into usual care settings, and investment in training the current and next generations of leaders in implementation. (Am Heart J 2025;286:18–34.)

Despite the development of highly effective therapies to improve cardiovascular health, disparities, variabilities in implementation, and delays in adopting these proven therapies persist. A notable example of substantial undertreatment is the current use of statins. High-intensity

statins were shown to be superior for secondary prevention of atherosclerotic cardiovascular disease (ASCVD) in randomized controlled trials in 2004 and 2005.^{1,2} In the decades since these definitive clinical trials, statins have become both generic and affordable, yet uptake remains poor, with only about 25% of patients with clinical ASCVD receiving high-intensity statins, accompanied by notable race and sex disparities in use.^{1,6} The prolonged journey of statins from clinical trial to clinical uptake unfortunately is not unique; similar trends have been seen in aspirin and beta-blocker use for acute myocardial infarction, which took over 30 years to reach the current levels of near complete adoption.⁷⁻¹¹ It is often cited that integrating research evidence into clinical practice takes an average of 17 years.^{10,11} However, the aforementioned examples suggest that achieving consistent adoption of evidence-based therapies may take even longer with some therapies having complete failure to adoption despite delays in time.^{12,13} Cardiovascular-kidney-metabolic (CKM) disease therapies have the potential to

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revolutionize how we combat cardiometabolic disease and associated risks through their demonstrated ability to reduce morbidity and mortality.¹⁴ This advancement necessitates the development of a more systematic and effective framework for the dissemination and implementation of evidence.

In response to the lack of adoption of evidence-based therapies, in the last 20 years, there has been a greater research focus on implementation. Implementation science is the study of methods to improve the systematic uptake of evidence into clinical practice.⁷ The intention is to improve not only the application of effective treatments but also health equity. Within implementation science, implementation strategies are designed to improve the scalable and sustained adoption of evidence.⁷

In recent years, there has been a substantial increase in cardiovascular studies that are using implementation science to reduce gaps in care.¹⁵ Despite the increasing number of cardiovascular implementation trials, there have not been adequate impacts in cardiovascular disease outcomes, as cardiometabolic mortality is on the rise.¹⁶ Further, differential adoption of guideline-recommended therapies is often seen in demographic and socioeconomic groups at highest risk for poor outcomes, including racial and ethnic minorities, the elderly population, low-income groups, and rural residents.^{6,17-22} Without adoption of evidence-based interventions in all communities, especially those most vulnerable, disparities may not just persist, but increase. Conversely, implementation efforts, when applied with careful attention to all populations, can improve care for all and improve overall health equity.²³⁻²⁵

Recognizing that implementation operates within a broad ecosystem, a collaborative approach that leverages the diverse perspectives and expertise of various stakeholders is vital to realizing the full potential to achieve meaningful improvements in practice. Accordingly, the Duke Clinical Research Institute (DCRI) convened a key group of 50 stakeholders for a one-day Implementation Summit on February 27, 2024, entitled “Scalability, Spread, and Sustainability” to explore ways to advance implementation science and the uptake of proven evidence-based interventions for cardiometabolic diseases across healthcare in the United States (U.S.). In attendance were leaders from insurance payors, the pharmaceutical industry, national quality programs, professional societies, editorial boards, health system leadership, academia, and research funding agencies. Summit participants reviewed current obstacles facing implementation and proposed four foundational pillars to address current implementation challenges: (1) fund, design, and produce more implementation research, (2) support targeted dissemination of evidence on treatment efficacy, (3) use stakeholder engagement and collaboration to enhance uptake, and (4) build implementation science capacity by training the next generation of ap-

plicators and leaders (Figure 1). The multidisciplinary group aimed to derive solutions across stakeholders that would accelerate the advancement, reach, and application of implementation science.

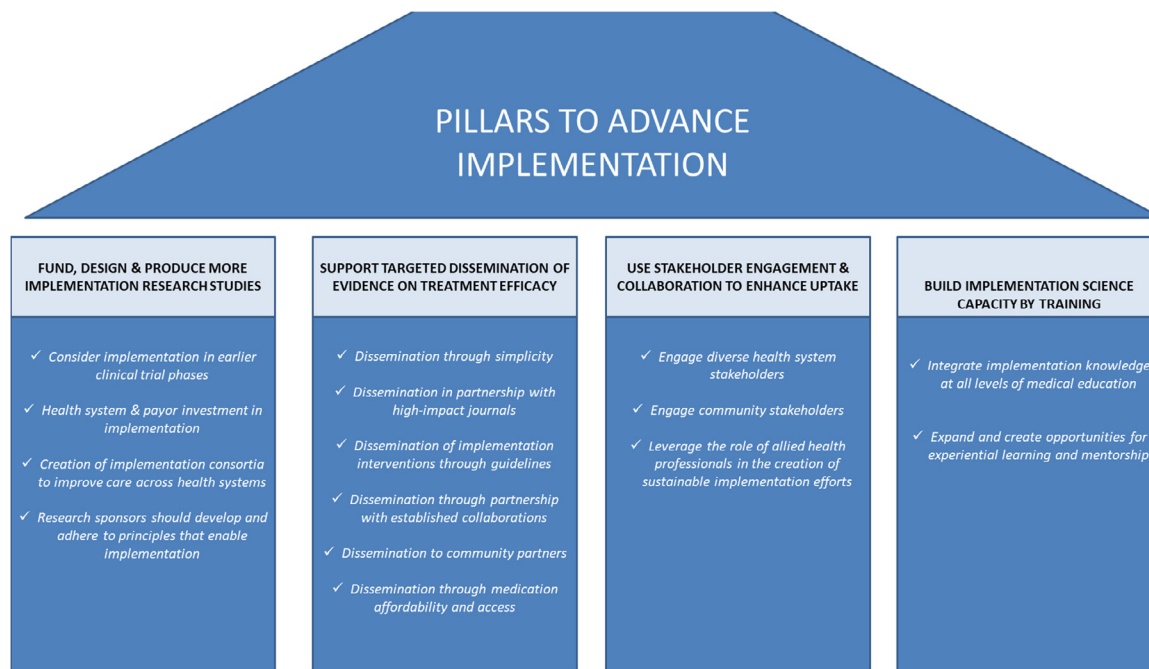
Key components and barriers to advancing implementation

Implementation science is the scientific study of how to integrate evidence into health care settings. It is defined not only by the use of models and frameworks but also by trials that identify effective implementation interventions that improve evidence uptake, with the ultimate goal of improving clinical outcomes. Dissemination is the distribution of information and strategies with the goal of impacting practice.²⁶ Population uptake refers to the initial uptake of the strategy into a large population, while scalability involves deliberate efforts to expand the impact of a successfully tested intervention to benefit a larger population.²⁷ Sustainability refers to the intervention impact continuing *beyond* the timeline of the clinical investigation; these considerations ask the question, “Does the information and/or intervention create the long-lasting desired effect in the intended population?”²⁸ Although uptake and sustainability are typically considered in the dissemination process, the integration of the results of implementation science into targeted communities requires considerable emphasis.

Implementation of evidence-based care for cardiometabolic conditions is hindered by the suboptimal application of implementation science, knowledge dissemination, population uptake/scalability and sustainability, and capacity building, including in workforce training, institutional support and infrastructure, project funding, and inclusion of implementation science in medical education curricula.²⁹⁻³¹ Dissemination hurdles include the absence of well-defined pathways to reach target populations, the challenge of introducing implementation interventions amidst competing priorities, difficulty in adapting evidence-based interventions to different clinical settings and patient populations that were not part of the original trial, and a failure to keep up with clinical updates regarding cardiometabolic disease treatment.^{30,32} Furthermore, there is inadequate measurement and feedback of uptake of the interventions within the desired population. Most importantly, there is a lack of collaboration between stakeholders that leads to siloed, slow progress.

To illustrate the distinct issues involved in different aspects of the implementation equation, we considered the gaps in treatment of heart failure. Projections estimate that by 2030, the prevalence of heart failure will increase by 46% compared to 2012.^{33,34} Estimates predict that the relative risk of mortality can be reduced by more than 70% with the use of guideline-directed medical therapy for heart failure with reduced left ventricular

Figure 1. Pillars to Advance Implementation – The advancement and scaling of implementation efforts rely on four foundational pillars: (1) increasing research production and funding, (2) strategically disseminating evidence, (3) engaging diverse stakeholders, and (4) strengthening implementation science capacity through training.



ejection fraction.³⁵ Nonetheless, less than 1% of such patients receive target doses of all four life-saving guideline-directed medical therapies (GDMTs), with larger gaps in uptake of target dose therapy in women and older adults.^{22,36-38} To address this GDMT gap, several randomized implementation trials have tested strategies to increase the use of guideline therapy. Specific implementation strategies that improve system-wide adoption of GDMTs have been identified, such as institutional financial incentives, heart failure specialty clinics, integration of nurses and pharmacists with algorithmic GDMT escalation, audit and feedback, digital technologies, and patient engagement.^{15,38-41} Despite this knowledge on which actions work, the chasm between knowledge and implementation still exists—even strategies proven in implementation trials are not being implemented in usual care settings.⁴² This example of treatment gaps in heart failure highlights that while there has been improvement in implementation science generation to reduce gaps in care, there are persistent gaps in heart failure outcomes, demonstrating problems with both dissemination and broad uptake.

We propose that advancing and scaling implementation can be divided into four pillar areas: (1) fund, design, and produce more implementation research, (2) support targeted dissemination of evidence on treatment efficacy, (3) use stakeholder engagement and collaboration to enhance uptake, and (4) build implementation science ca-

capacity by training the next generation of applicators and leaders

Pillars of advancing implementation

Pillar I: Fund, design, and produce more implementation research

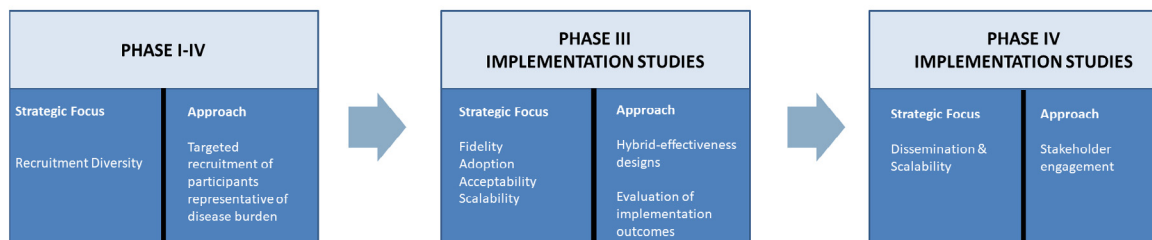
Consideration of implementation in earlier clinical trial phases

Implementation trials generate scientific knowledge aimed at improving the adoption of evidence-based interventions in clinical practice. For a medication or innovation to come to market or enter the healthcare system, it must undergo several phases of clinical trials: phase I (safety), phase II (effectiveness, dose exploration, and side effects), phase III (comparison to current standards), and phase IV (post-marketing surveillance). Currently, if the implementation of a therapy is considered, it is usually late in the development process, often after the product has come to market. As part of the first pillar on increasing implementation research, we recommend that implementation should be considered earlier in clinical trial phases to facilitate readiness for a therapy to be received by the target population in a fast and equitable manner (Figure 2).

The first consideration, pertinent to all clinical trial phases, is recruitment of a representative participant cohort for the condition under study across demographic,

Figure 2. Optimal Timing for Introducing Implementation Science in Therapy Development – Implementation science can be integrated at various phases of drug therapy and device development, with the strategic focus and approach varying by phase. Key approaches include diverse participant enrollment, incorporation of hybridism or full implementation trials, evaluation of implementation outcomes, and stakeholder engagement.

When to Introduce Implementation Science into Therapy Development?



clinical, and socioeconomic characteristics. Inclusive enrollment improves generalizability of efficacy and safety estimates, and it may increase patient trust in the medication or intervention. In cardiovascular and kidney disease trials with drugs approved by the Food and Drug Administration in 2020, White individuals were overrepresented, at 73.7% of participants, and women represented less than 50% of participants.⁴³ Additionally, individuals aged 65 years and older remain consistently underrepresented in clinical trials for heart failure and venous thromboembolism.⁴⁴ Those in historically marginalized groups are also often disproportionately underrepresented.^{43,45,46} The lack of representative enrollment in clinical trials is partly related to trial design and not specific to cardiometabolic disease, however these underrepresented groups bear a higher burden of cardiometabolic disease, making diversity in enrollment through more thoughtful trial design a priority in cardiometabolic trials.^{43,45,47}

The current practice of considering how best to implement therapies in phase IV during the post-marketing period is insufficient. phase III provides the opportunity to examine implementation outcomes (e.g., implementation cost, fidelity, feasibility, and appropriateness) along with identifying the efficacy of a therapy.⁴⁸ Various trial designs can incorporate implementation principles. Pure implementation trials focus on the effectiveness of an intervention, while explanatory clinical trials aim to determine efficacy. Hybridism allows trialists to integrate the evaluation of effectiveness into clinical trials that are primarily designed to determine efficacy. Hybrid effectiveness-implementation designs integrate research questions regarding the efficacy of an intervention with questions on how best to implement it.⁴⁹ The hybrid framework guides the study to evaluate implementation-related factors (e.g. barriers and facilitators to implementation), testing of the impact of an implementation strategy on implementation outcomes

(e.g. cost, feasibility, fidelity, and intervention delivery), or both—all while testing and gathering information on the effectiveness of the medication.⁴⁹ It is also important to prioritize stakeholder engagement, particularly within disadvantaged communities that bear a disproportionate disease burden. Approaches may involve co-design of how the therapy should be delivered in the clinical setting and strategizing on how to increase recruitment of the desired population. This process should address trialists’ limited understanding of community beliefs and practices, as well as the prevalent mistrust within communities toward clinical research. Additionally, the process should focus on developing targeted strategies to build trust that are specific to the therapy being evaluated. Moreover, healthcare professionals and health system leaders should be included in the co-design process to identify and address barriers and facilitators to clinical workflows. Qualitative methods should be employed to examine the factors that influence adoption of the therapy, whether positively or negatively.^{50,51}

Additionally, trialists of large phase III trials should consider incorporating methods to model the heterogeneity of the treatment effect, enabling the generation of personalized outcomes estimates for individual patients or patient subgroups. These estimates can be incorporated into decision-support systems and patient-facing shared decision-making tools to translate population-level average treatment effects into clinically meaningful guidance for individual care. While randomized clinical trials provide good estimates of average treatment effects—the difference in average outcomes between the group treated and the group not treated with the intervention or therapy of interest, they are less adept at capturing the variability in treatment effects across diverse patient subgroups.

For example, the International Study of Comparative Health Effectiveness with Medical and Invasive Approaches (ISCHEMIA) Trial randomized patients with sta-

ble coronary artery disease (CAD) to receive either an invasive strategy (angiographic assessment and revascularization if indicated) alongside GDMT or a conservative strategy with GDMT alone. The primary outcome showed no difference in cardiovascular events or death during the follow-up period.⁵² However, the key secondary outcome indicated that an invasive approach in high-risk patients may result in improvements in health status in those with angina refractory to medical therapy.⁵³ To better leverage the data from the ISCHEMIA trials to support guideline-recommended shared decision making,⁵⁴ models for the heterogeneity of treatment benefit were built and a stakeholder-informed, single-page shared decision-making tool was created so that patients and clinicians could leverage the data from the ISCHEMIA trial to support an informed selection of a treatment strategy that most aligns with the patient's values and goals.⁵⁵⁻⁵⁷

Research sponsors should develop and adhere to principles that anticipate implementation needs

Research sponsors can establish expectations for the research they fund. Leveraging this influence, research sponsors should consider developing guidance that supports implementation trials and/or hybrid designs, requirements for implementation principles across trials, and professional development awards for implementation science to build capacity. Sponsors may also support the formation of community partnerships to participate in the design of therapy delivery, recruitment outreach, and, ultimately, a dissemination plan for populations in need of the therapies.

Health system and payor investment in implementation of evidence

While research sponsors play a crucial role in supporting the development of implementation science, health systems and insurance payors are also key fulcrums for developing or scaling effective implementation strategies. Health systems are fertile ground to locally test and rapidly scale proven implementation strategies to decrease the evidence-to-practice gap in a cost-effective manner.

Health systems fall short when patients hospitalized for heart failure are discharged without evidence-based medications known to reduce costly readmission or when strategies to improve adherence to guideline therapy solely rely on education. Due to rising hospital costs and issues with overall healthcare affordability, hospitals and health systems are increasingly entering into value-based risk contracts with payors, which incentivizes the development of new care delivery models that are patient-centered, cost-efficient, and equitable. Financial arrangements such as value-based risk contracts can serve as a means for health systems to prioritize investing in implementation and delivering effective and high-value treatments. The return on investment in scaling implementation in health systems for cardiometabolic conditions

could be reductions in both patient and societal costly outcomes including re-hospitalizations, kidney failure, and cardiovascular disease events. It is in a health system's best interest to prioritize investments in evidence implementation, specifically therapies and interventions known to reduce readmissions. This is especially critical in models where hospitals bear financial responsibility for readmissions. A study examining Medicare beneficiaries with multiple admissions for similar diagnoses within a year isolated the effect of hospital-specific readmission rates.⁵⁸ The findings showed that patients admitted to hospitals with poorer performance on readmissions were more likely to experience a readmission within 30 days, even when presenting with comparable diagnoses. This suggests that local health system deployment of evidence-based interventions may meaningfully affect outcomes.

Insurance payors have a vested interest in the deployment of evidence-based treatments in cardiometabolic conditions due to the high costs of cardiovascular disease events and care. National cost analyses derived from hospital discharge data indicate that admissions for heart failure and myocardial infarction are among the highest contributors to annual healthcare expenditures.⁵⁹ In 2011 alone, there were 3.3 million hospital readmissions, with an associated cost of \$41.3 billion, prompting the Centers for Medicare and Medicaid Services (CMS) to establish the Hospital Readmission Reduction Program with the aim of tracking and reducing readmissions of six conditions, including three related to cardiovascular disease: myocardial infarctions, heart failure, and coronary artery bypass grafting.⁶⁰ Despite these efforts, the program has not made meaningful success in reducing 30-day readmissions, emphasizing the need for a more comprehensive, multifaceted strategy—extending beyond financial penalties—to address the factors of poor adoption of evidence-based therapies and to improve patient care.⁶¹

On the other hand, a system-wide investment in implementation strategies and evidence-based medicine that leads to lower heart failure and post-percutaneous interventions readmissions has the potential to be cost-saving to the health system and insurer. National estimates indicate that approximately 1 in 7 patients undergoing percutaneous intervention is readmitted within 30 days, often due to reinfarction/stent thrombosis, heart failure, chest pain, or bleeding, with an average cost per readmission ranging from \$12,636 to \$17,575.⁶² An estimated 40% of these readmissions may be preventable with improved care coordination, making readmissions an appealing performance target.⁶² A notable example of an insurer-driven investment in health system implementation of evidence is the Blue Cross Blue Shield Michigan Cardiovascular Consortium (BMC2) that launched in 1996. Initially a five-hospital initiative aimed at improving cardiovascular outcomes, BMC2 has expanded

into a statewide consortium.⁵⁹ The creation of registries and multi-center learning collaboratives focused on improving regional quality as well as collecting, auditing, and reporting data to both physicians and hospitals has been associated with fewer hospital readmissions after coronary revascularizations, improved long-term outcomes, and reduced health care costs.⁵⁹ In 2017, BMC2 launched a multi-year initiative specifically targeting post-percutaneous coronary intervention (PCI) readmissions, which resulted in a decline in readmissions and \$5.75 million dollars in annual cost savings.⁶³ Given the success with BMC2, Blue Cross Blue Shield Michigan has expanded its value partnership to 20 clinical areas across more than 100 hospitals, introducing new payment models that reward healthcare professionals for achieving better outcomes. Over the past 20 years, these partnerships have saved the insurer an estimated \$6.3 billion in healthcare expenses.⁶⁴

Creation and funding of implementation consortia to improve care across health systems

Some approaches to improving implementation have been led by professional societies using their clinical registries for measurement and feedback, such as the National Cardiovascular Data Registry and the Get with the Guidelines Registry. These programs enable benchmarking, allowing hospitals and healthcare professionals to compare their outcomes with those of their peers, with the goal of motivating improvements in patient care.^{65,66} However, to further advance implementation and enhance outcomes, professional societies should consider further expanding the use of their data by developing more tools designed to prospectively improve care, including in institutions that lack the resources to improve outcomes on their own. Mission: Lifeline, a collaborative program developed in partnership with the American Heart Association and hospitals, serves as a model of a large-scale program that made an important impact on acute myocardial infarction care. Mission: Lifeline used a comprehensive approach to improving first-medical-contact-to-device time by establishing leadership teams, creating coordinated protocols, and providing feedback to 484 hospitals and over 1200 emergency medical service agencies nationwide, leading to lasting improvements in acute myocardial infarction care in a short time.^{67,68} The strength of these initiatives lies in data-sharing, learning from collective experiences, and tailoring of implementation strategies to local contexts. By harnessing these capabilities, professional societies have the potential to create nationwide consortia that leverage shared data and insights. These consortia could provide a scalable infrastructure for driving innovation in implementation science and improving healthcare outcomes on a national scale.

As one example of a successful consortium, in 2019, several large U.S. health systems established the Cardiovascular Quality Improvement and Care Innovation Con-

sortium (CV-QUIC), a multicenter collaborative focused on developing, evaluating, and disseminating innovative care delivery solutions to improve quality of care across health systems.⁶⁹ Through this collaboration, leaders in health system quality created and rapidly disseminated novel methods of delivery of care using implementation strategies that have led to cost reductions amongst the health systems. Notable achievements included improving scheduling of 14-day follow up appointments after heart failure hospitalizations from 43% to 93% and implementing an electronic health record integrated heart failure discharge checklist that reduced readmission rates by 3%.^{69,70} Another effort aimed at improving implementation is the CardioHealth Alliance, a nationwide consortium including health systems and industry partners that conducts clinical trials within the consortium to further understand cardiometabolic conditions, develop new evidence-driven care pathways to improve outcomes, and improve implementation.⁷¹

Pillar II: Support targeted dissemination of evidence on treatment efficacy

Despite the development of highly efficacious treatments and the recent efforts to improve implementation, discontinuity still exists in the generation of evidence and the process of disseminating discoveries into practice settings.⁷² Passive approaches to dissemination are generally ineffective.⁷³ Common dissemination methods include publications of results in academic journals (100%), presentations at academic conferences (95%), and reports issued to funders (78%).⁷² Industry sponsors also engage in direct dissemination of evidence to healthcare professionals and patients, often through direct-to-consumer advertising of prescription drugs—practices that are not permitted in many countries and whose effectiveness remains unclear. Further research is needed on how to target specific health care professionals and patients. As the second pillar, we recommend focused efforts to improve the dissemination of evidence, emphasizing more active and tailored approaches to ensure its broader and more effective application in clinical practice.

Dissemination through simplicity

To increase the initial uptake of effective therapies and ultimate sustainability, we must make implementation of effective therapies more accessible, easier, and adherent to the path of least resistance. Implementation strategies must improve operational efficiencies and minimize additional steps. Being shown a better way that also reduces the burden of practice should accelerate acceptance and improve sustainability.

Interventions should be designed to be easily disseminated. As discussed above, phase III trials could model the heterogeneity of the treatment effect and the subsequent integration of findings into decision-support systems. Additionally, trialists should publish streamlined,

step-by-step policies and procedures used to implement the study agent or device in the form of appendices or supplements in publications and reports. The procedures should be written to facilitate scalability from individual clinics to larger hospital systems and should incorporate standardized performance assessment metrics to enable the tracking and comparison of outcomes across settings. Similarly, guidelines must incorporate the same practical guidance, i.e., “how to” implementation procedures, in addition to the traditional “what to do” guidance of formal guideline documents.

Another important consideration in the dissemination of information on effective therapies is the simultaneous emphasis on de-implementing low-value, ineffective, and inappropriate medical therapies to lessen the clinical burden.⁷⁴ Two key factors that influence the de-implementation of health interventions include strength of evidence and level of complexity. Priority should be given to actively de-implementing therapies and interventions that exhibit varying degrees of evidentiary support, particularly those that have been shown to be ineffective or that remain untested.⁷⁵ Furthermore, focusing on low-complexity interventions offers a good starting point for de-implementation.

Last, in the world of artificial intelligence, we should design tools that will allow us to rely less on individual knowledge acquisition and recall and that will instead prompt healthcare professionals to choose medications based on established evidence. These tools, once tested, can be incorporated into the electronic health record optimized order sets and bundles with the assistance of informaticists. For example, in a new patient with heart failure and chronic renal disease, electronic health record artificial intelligence tools would prompt the healthcare professional to initiate an SGLT-2 inhibitor, and if not initiated, these tools would require action from the professional to indicate why a GDMT was not prescribed. The medical field is currently experiencing a significant clinical workforce crisis, particularly among physicians, with notable shortages of cardiologists and other specialists who provide complex cardiometabolic care.⁷⁶⁻⁷⁸ Paradoxically, an unintended consequence of team-based care may be the exacerbation of knowledge gaps. If the managing physician fails to close a knowledge gap, the impact on other team members may be to inadvertently perpetuate or amplify the same knowledge gap(s). This “top-down” propagation of knowledge deficiencies poses a significant challenge that may be overcome by technology that works to suggest efficacious and guideline-based therapy.

Dissemination in partnership with high-impact journals

To increase the visibility and impact of implementation science for cardiometabolic conditions, there is a need to partner with journals to discover new ways to inform health professionals and the public. Currently, publica-

tion in academic journals serves as the primary method to disseminate research findings.^{73,79} However, with the rise of social media propagating the rapid spread of disinformation and misinformation and with a growing desire for the public to know and understand health information, the current information climate provides an opportunity to try novel and transformative dissemination tactics.⁸⁰ Peer-reviewed, high-impact medical journals are highly regarded by health care professionals, and in this information frenzy, journals could consider more novel techniques for direct-to-patient outreach with the aim of explaining the results of practice-changing trials to combat misinformation and increase public trust in scientific evidence generation. Although some journals provide patient-directed educational materials, known as patient pages, these resources are often inaccessible to the intended audience. Consequently, much of the public relies on interpretations of trial results disseminated through broadcast news and social media, which may lack accuracy.

Dissemination to clinicians through guidelines

Clinical practice guidelines serve as a key tool for clinicians to understand evidence-based treatments for patients. Guidelines cannot be used in isolation, as they alone do not confer clinical practice adoption; rather, guidelines provide a central resource for the summary of evidence. The presence of evidence in guidelines provides gravitas. Although cardiometabolic guidelines have begun to provide value statements for recommendations when there are published high-quality or cost-effectiveness studies, more should be done to prompt and guide users to consider implementation.⁸¹ It is important for guidelines to include implementation strategies that have been proven effective in improving the application of effective treatments. The National Heart, Lung and Blood Institute (NHLBI) Implementation Science Working Group (ISWG) was charged with assessing evidence-based strategies aimed at the clinician level and assessed the underlying evidence for effectiveness, cost considerations, and contextual barriers. Their findings, published in the 2017 American College of Cardiology/American Heart Association Special Report, highlighted the general effectiveness of audit and feedback as well as educational outreach visits while showing mixed results for clinician incentives and reminders.⁸² Since 2017, additional trials have demonstrated the effectiveness of implementation strategies. A recommendation from the participants of the Implementation Summit is that the NHLBI convene another working group to update clinicians with the latest findings, needs, and recommendations around implementing GDMTs.

Dissemination through partnership with established collaboratives

Collaborations should extend beyond cardiometabolic professional societies to include partnerships with organizations that have demonstrated excellence in informa-

tion dissemination. The Institute for Healthcare Improvement (IHI), founded in 1991, is a non-profit organization that equips health systems and providers with tools, methods, and training to redesign local systems, thereby improving patient safety, promoting equity, and reducing costs. The IHI has established a systematic approach to rapidly disseminating information and driving meaningful change.

In December 2006, the IHI launched a nationwide initiative aimed at preventing 100,000 unnecessary deaths within two years.^{83,84} This goal was exceeded through partnerships with over 3000 hospitals—representing nearly 75% of hospitals nationwide—by offering expert guidance, educational resources, and support at no cost. The initiative focused on strategies such as implementing Rapid Response Teams, improving care for myocardial infarction, and preventing central line infections, surgical site infections, and ventilator-associated pneumonia. Another non-profit organization that has shown success in the rapid dissemination of information is Project ECHO (Extension for Community Healthcare Outcomes), a collaborative model of medical education and care management that helps professionals provide specialty-level care to rural and underserved areas.^{84,85}

Partnering with successful organizations like the IHI and Project ECHO could provide valuable insights into effective information dissemination strategies. Learning from their proven methods of rapid dissemination could inform improvements in the implementation of evidence-based practices across diverse healthcare settings.

Dissemination to community partners

Establishing, building, and nurturing trust have been identified as essential to achieving high levels of engagement within communities.⁸⁶ Trust in research has been defined as the willingness of participants to be vulnerable to the actions of another party, irrespective of the ability to monitor or control the other party.⁸⁷ Although safety (consequences of participation), communication (quality and nature of information exchange), and fairness (perceived treatment of disadvantaged groups) have been identified as important domains of trust to be enhanced in the research setting, trust on the individual level is influenced by educational level, cultural beliefs, and personal experiences.^{88,89} Conventionally, within research, emphasis is placed on the public's lack of trust of research, with the question being, "What can be done to improve *their* trust in research?" However, researchers play a vital role in garnering the public's trust, thus prompting the mindset shift to ask the question, "*Are the researchers themselves trustworthy?*"⁸⁶

Strategies to enhance participant trust include balancing of power dynamics, equitable distribution of resources, bidirectional communication, shared-decision making, and valuing of lived experiences and group norms.⁸⁶ Characteristics of trustworthy researchers in-

clude being accessible, approachable, honest, and humble.⁸⁶ As the dissemination of research to community partners increasingly demands more researcher-facing community engagement, there must be a concerted effort by researchers to present themselves as individuals worthy of trust. An important extension of these efforts includes the incorporation of community representatives and patient advocates into research teams. This addition ensures that the voices and perspectives of those directly affected are considered throughout the research processes, helping to foster more inclusive and trustworthy practices and approaches.

For community partners, it is important to create a dissemination team consisting of researchers, the target audience, and, if possible, communication experts. Targeted dissemination to community partners provides the knowledge for patients to be advocates for their own health. The science should be distilled to a small bite-sized message, for example, "If a patient has heart failure, what will this new medication do for the patient?" Dissemination methods should be catered to the target audience and should include multiple outlets, such as a digital presence, including on social media, and the use of trusted news outlets such as local news channels, radio, and community agency newsletters.^{90,91}

Dissemination through medication affordability and access

Medication access and affordability constitute a critical barrier to population-level uptake and long-term sustainability of select therapies. Various factors influence affordability, including procurement costs, purchasing power, price regulation, domestic manufacturing capacity, and the availability of generic options.⁹² An international evaluation of the affordability and uptake of GDMTs for heart failure with reduced ejection fraction highlighted substantial variation in drug prices across ten countries. Notably, the cost of angiotensin receptor-neprilysin inhibitors (ARNIs), such as sacubitril/valsartan, showed significant international disparities, with mean 30-day retail cost ranging from \$11.06 in Pakistan to \$611.50 in the United States. Such pricing variability limits the widespread adoption of ARNIs.⁹² Within the U.S., additional factors such as tiered insurance coverage, deductibles, and copayments further exacerbate access challenges. Due to cost constraints, angiotensin-converting enzyme inhibitors (ACEis) and angiotensin receptor blockers (ARBs) are often more cost-effective alternatives, facilitating broader implementation despite their relatively lower efficacy compared to ARNIs. These findings underscore the need for strategies to improve affordability and equitable access to high-value therapies.

Addressing cost requires a multifaceted approach. First, medication developers must prioritize patient affordability for highly effective therapies. While pharmaceutical companies often offer medication assistance

programs to underinsured or uninsured patients as part of corporate social responsibility efforts, these programs are typically complicated for patients and professionals, time-limited, and insufficient to cover costs until medications become generic. Extending the duration of these programs would represent a meaningful step toward improving access.

Second, legislative action is essential to facilitate broader cost reductions. In the U.S., the Inflation Reduction Act of 2022 made a significant step in the right direction by capping out-of-pocket medication costs for Medicare Part D beneficiaries at \$2,000 and enabling the CMS to negotiate drug prices. Among the first ten medications selected for negotiation, six are used for cardiometabolic conditions.⁹³ Expanding price negotiation capabilities within Medicare and to private insurance can alleviate patient cost-sharing burdens and enhance access to life-saving therapies for vulnerable populations.

However, a persistent challenge lies in the reluctance of insurance payors to cover effective new therapies promptly. Commercial insurers often fail to realize the return on investment for novel treatments, diagnostics, and devices within the short coverage periods of 18–24 months, leading to hesitancy in adoption and deferral of risk reduction to a later point in time. To address this issue, regulations or financial incentives should be introduced to accelerate the coverage of highly effective medications, therapies, and diagnostics. Additionally, barriers such as prior authorization requirements should be minimized to streamline patient access and enhance the timely implementation of innovative treatments.

Pillar III: Use stakeholder engagement and collaboration to enhance uptake

Implementation is usually setting-specific; thus, engagement of stakeholders should be tailored to the location of the planned intervention. There are different degrees to which stakeholders can be involved in implementation. Engaged participation is the highest and most desired tier, when all stakeholders have shared decision-making authority in various phases of study design, recruitment, process evaluation, dissemination strategy, and uptake measurement.^{94,95} Consultation, or asking partners for advice on important aspects of a project, is the most used level of engagement, while engaged participation or partnership is the least common and only used 3% of the time.⁹⁶ The Summit highlighted ways to partner with insurance payors, research funding agencies, health systems, researchers, and community partners to advance implementation. Building on these foundational partnerships is crucial to the success of implementation, forming the basis of our third pillar.

Engage diverse health system stakeholders

Developing an intervention that engages multiple stakeholders may initially appear complex or challenging, but effective stakeholder participation can be pivotal

for both the uptake and long-term sustainability of the intervention. An example of this is the national effort to reduce door-to-balloon (D2B) and first medical contact-to-device times for primary PCI, which is highly dependent on timely execution for optimal efficacy.⁹⁷ Clinical practice guidelines recommend a first medical contact-to-device time of no more than 90 minutes; however, in 2002, only one-third of patients received PCI within this timeframe.⁹⁸

The suboptimal D2B performance prompted a national response (2002–2008) that involved multiple coordinated efforts. These included the adoption of a CMS quality measure, research identifying organizational strategies associated with reduced D2B times (e.g., single-call catheterization laboratory activation, rapid feedback systems, and administrative support), and the launch of the D2B: An Alliance for Quality initiative by the American College of Cardiology in collaboration with 38 other organizations.^{98,99} These combined efforts led to a dramatic improvement, with median D2B times decreasing by 32 minutes, reaching a national median of 64 minutes between 2005 and 2010—well below the 90-minute target.⁹⁸

The rapid success, early adoption, and sustainability of these interventions were largely due to diverse stakeholders who efficiently collaborated on the intervention. Key stakeholders included federal agencies, hospital administrators, clinical investigators, emergency medical services personnel, emergency department staff, cardiologists, catheterization laboratory teams, and quality improvement professionals. Effective engagement and collaboration among these stakeholders were instrumental in achieving sustainable improvements in reperfusion times, underscoring that leveraging stakeholder input and participation has the potential to be a strength rather than a challenge.

Engaging community stakeholders

There remains a lack of buy-in from communities regarding the incorporation of evidence and proven implementation strategies, perhaps due to suboptimal community engagement. Community partners are not just the “gatekeepers” of a community; they are also the key to enhancing uptake of a therapy at the community level.⁹⁵ To address health inequities, careful attention should be taken to include representation from the general population as well as those affected by the condition and associated disparities. Ideal community partners are involved in social networks embedded in the target community. They are those who are committed and willing to use their unique social capital to provide insight into pervasive medical mistrust and ways to establish trust, participate in co-design of the project to best work in their community, and enhance the dissemination process. Black churches are the epitome of community partners given their interlocking ties with the African American communities, a minority population known to ex-

perience a high burden of cardiometabolic conditions. Church-based interventions have been effective in reducing cardiometabolic risk factors.¹⁰⁰ An example of involving community leaders in research co-design and recruitment is the partnership of the African Methodist Episcopal (AME) Zion church, a predominantly Black church with over 300,000 congregants in North Carolina, with Duke University in Durham, North Carolina; in this health equity partnership, clergymen representing over 15 AME congregations advise on designing approaches to community research including the Black community, co-designing trials, and recruitment of Black participants.¹⁰¹

Additionally, the roles of allied health professionals (e.g. as care coordinators, patient navigators, community health workers, and local pharmacists) should be defined, and it should be determined how their roles could be leveraged to create sustainable implementation efforts within a community. The role of allied health professionals is underrecognized and underutilized in assisting in improving outcomes in the U.S.¹⁰² Community health workers (CHWs) are valuable assets to the healthcare workforce, as they are trained to have basic knowledge of clinical conditions and have expertise in assisting patients with health care access. Typically employed by state health departments, CHWs augment patient engagement by strengthening ties with health care and increasing the number of patients who access services.^{103,104} The role of CHWs remains untapped, but employment of CHWs has demonstrated utility in a reduction in health care utilization, cost, and hospital readmission rates.^{103,105,106} A notable example of engagement of effective community partners and allied health professionals to improve outcomes is the partnership between Black barbers and local pharmacists in a cluster-randomized trial of blood pressure control in barbershops.¹⁰⁷ The pharmacist-led intervention resulted in an over 20-point reduction in systolic blood pressure in uncontrolled participants, with a 95% retention rate.¹⁰⁷ Success lies in community uptake, leveraging trustworthy individuals who are closest to those who have the potential to be impacted.

Pillar IV: Build implementation science capacity by training the next generation of applicators and leaders

The fourth and final pillar is the investment in the education and training of the next generation of implementation experts, with a focus on supporting the development of a standardized curriculum to teach the foundational principles of implementation science throughout the medical education continuum, including medical school, graduate medical education, and continued medical education. Accreditors for medical education have historically played a crucial role in successfully setting standards for clinical competencies for training and en-

hancing the knowledge base of health care professionals in rapidly evolving fields such as quality improvement and patient safety.¹⁰⁸ By tying curricular mandates to program accreditation, accreditors have effectively leveraged their authority to play an important role in the rapid integration and adoption of new ideas into the minds of future and current physicians.^{42,108-110} Similar efforts at a systematic level are needed to embed implementation science, strategies, and proven therapies into the medical education spectrum. Moreover, as cardiology transitions to a new cardiovascular board for the initial and maintenance certification, there will be an emphasis on identifying and closing knowledge gaps. Certification exams must evaluate physician competencies in managing change and implementing new therapies.^{111,112}

At the same time, for academic researchers, increased opportunities for experiential learning and mentorship are needed. The National Institutes of Health (NIH) remains one of the largest funders of implementation science and now has a standing set of opportunities (e.g. an annual conference on dissemination and implementation research in cancer, and career development awards).¹¹³⁻¹¹⁵ More opportunities for experiential learning are needed to arm researchers with the knowledge needed to apply implementation methodologies and practice to research.

Future directions

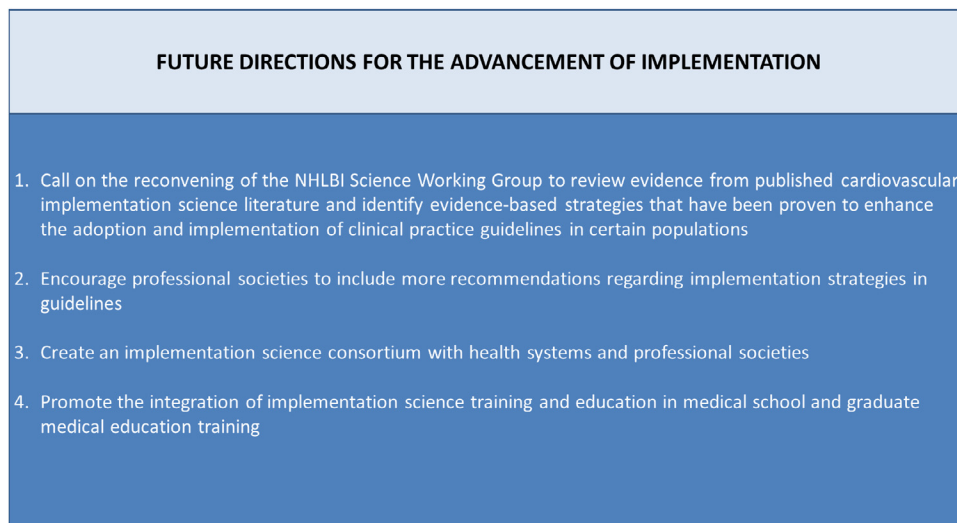
This manuscript outlines four foundational pillars to elevate and accelerate the implementation of evidence-based therapies for CKM conditions. To strengthen the four pillars, there are crucial steps that must be taken (Figure 3).

First, the past decade has seen an increase in effective implementation strategies in the cardiometabolic field. To advance further, it is imperative to establish a consolidated, reliable source for disseminating effective implementation strategies. An updated NHLBI Implementation Science Work Group special report is recommended.

Second, proven implementation strategies should be incorporated into clinical practice guidelines as a step toward promoting widespread dissemination. Ensuring that these strategies are visible in guideline recommendations will further promote adoption in clinical practice.

Third, we recommend the establishment of national consortia, led in part by professional societies and in collaboration with successful dissemination organizations such as the IHI and Project ECHO, to institute, evaluate, and scale up implementation. While we recognize the potential for long-term improvement in quality of care and cost reductions, one critical gap in current implementation efforts is a lack of clarity regarding investments. Quantifying both the initial costs required to implement GDMTs and the subsequent savings from reduced care utilization is essential for driving adoption.

Figure 3. Future Directions for the Advancement of Implementation Science- Immediate actions that can be taken to advance implementation science and the implementation of evidence.



Fourth, we must integrate implementation science and its link to improving guideline-directed care into medical and graduate medical education. Training future clinicians and researchers in the principles and practices of effective implementation will be important for sustaining progress and ensuring that GDMTs reach the target populations.

Conclusion

Implementation and dissemination science are needed to improve the use of guideline-directed care and to reduce health disparities in a cost-efficient manner. Collaboration among stakeholders offers a multifaceted, comprehensive approach to addressing these challenges. However, for patients to fully benefit from improved implementation, a comprehensive shift is required. This includes increasing implementation research and targeted dissemination efforts that leverage stakeholder involvement and training the next generation to drive meaningful progress.

Declaration of competing interest

Hayden Bosworth received funds from Duke University for travel to the Summit meeting; grants paid to his institution (not related to the reported work) from BeBetter Therapeutics, Boehringer Ingelheim, Esperion, Merck, Improved Patient Outcomes, National Institutes of Health, Novo Nordisk, Otsuka, Elton John Foundation, Sanofi, Pfizer, Veteran Health Administration, and Hilton Foundation; and consulting fees (not related to the reported work) from Webmed, Walmart, Imatar, Sanofi, and Boehringer Ingelheim. He was previ-

ously a member of the Board of Directors of Preventive Diagnostics.

Samual Fatoba was an employee of Bayer LLC at the time of the meeting and manuscript preparation.

Lee Fleisher worked as the Founding Principal of Rubrum Advising, which advises medical device companies on coverage, but there is no specific conflict with any of the technologies discussed in the manuscript. He was previously CMS, CMO, and Director of the Center for Clinical Standards and Quality.

Edward Fry participated on a Data Safety Monitoring Board for Safe and Timely Antithrombotic Removal - Ticagrelor (START Trial) DSMB 2021-2023, served as President of the American College of Cardiology (2022-2023), and was a board member of the American Board of Cardiovascular Medicine (2024-present).

Christopher Granger has consulted for Abbvie, Abiomed, Alnylam Pharmaceuticals, Amgen, Anthos, Bayer, Boehringer Ingelheim, Boston Scientific, Bristol Myers Squibb, Cardionomic, CeleCore Therapeutics, HengRui, Janssen, Lilly, Medscape, Medtronic Inc., Merck, NIH, Novo Nordisk, NephroSynergy, Novartis, Pfizer, Philips, REATA, Roche, and Veralox; has received research grant support from Alnylam, Boehringer Ingelheim, Bristol Myers Squibb, FDA, Janssen, Lilly, Novartis, Pfizer, Philips, and Roche; and has equity in Tenac.io.

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Vincent Willey is employed by Carelon Research, which has received funding from multiple life science companies to perform research studies evaluating topics in the cardiovascular-kidney-metabolic therapeutic area.

CRediT authorship contribution statement

Nkiru Osude: Formal analysis, Writing - original draft, Writing - review & editing, Conceptualization, Data curation. **Harriette Van Spall:** Conceptualization, Data curation, Formal analysis, Writing - original draft. **Hayden Bosworth:** Conceptualization, Data curation, Formal analysis, Writing - original draft. **Konstantin Krychtiuk:** Conceptualization, Data curation, Formal analysis, Writing - review & editing, Writing - original draft. **John Spertus:** Writing - review & editing, Writing - original draft. **Samuel Fatoba:** Writing - review & edit-

ing. **Lee Fleisher:** Writing – review & editing. **Edward Fry:** Writing – review & editing. **Jennifer Green:** Writing – review & editing. **Stephen Greene:** Writing – review & editing. **Michael Ho:** Writing – review & editing. **Jennifer Jackman:** Writing – review & editing. **Jane Leopold:** Writing – review & editing. **Melissa Magwire:** Writing – review & editing. **Darren McGuire:** Writing – review & editing. **George Mensah:** Writing – review & editing. **Katherine R. Tuttle:** Writing – review & editing. **Vincent Willey:** Writing – review & editing. **Neha Pagidipati:** Writing – original draft, Writing – review & editing, Conceptualization, Data curation, Formal analysis. **Christopher Granger:** Writing – review & editing, Conceptualization, Data curation, Formal analysis.

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