



Value in Healthcare Initiative

Summary and Key Recommendations

ABSTRACT: In spring 2018, the American Heart Association convened the Value in Healthcare Summit to begin an important conversation about the challenges patients with cardiovascular disease face in accessing and deriving quality and value from the healthcare system. Following the summit and recognizing the collective momentum it created, the American Heart Association, in collaboration with the Robert J. Margolis Center for Health Policy at Duke University, launched the Value in Healthcare Initiative—Transforming Cardiovascular Care. Four areas of focus were identified, and learning collaboratives were established and proceeded to conduct concrete, actionable problem solving in 4 high-impact areas in cardiovascular care: Value-Based Models, Partnering with Regulators, Predict and Prevent, and Prior Authorization. The deliverables from these groups are being disseminated in 4 stand-alone articles, and their publication will initiate further work to test and evaluate each of these promising areas of reform. This article provides an overview of the initiative's findings and highlights key cross-cutting themes for consideration as the initiative moves forward.

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Cardiovascular disease (CVD) remains the leading cause of death in the United States,¹ and after 40 consecutive years of reductions in cardiovascular mortality rates, there has been a worrisome upswing in the past 5 years. Access to care and clinical outcomes vary nationwide, with significant disparities between minority and white populations and between urban and rural ones in cardiovascular outcomes.²⁻⁴ Further, the costs of care continue to rise between 1996 and 2014, total cardiovascular expenditures increased by nearly 150%, and the American Heart Association (AHA) estimates that direct costs for CVD care reached \$318 billion in 2015. Compounding these problems, investment in innovation for new CVD treatments is lagging behind other clinical areas such as oncology.⁵ There is thus a clear need to improve outcomes and reduce costs—to improve value—for CVD.

In spring 2018, the AHA convened the Value in Healthcare Summit to begin a conversation around finding solutions to the challenges faced by patients with CVD in accessing and deriving quality and value from the healthcare system. Leaders from across healthcare came together and created a shared vision for the healthcare system of the future, described by the group as its moral imperative on behalf of the patient public. The AHA, in collaboration with the Robert J. Margolis Center for Health Policy at Duke University, then launched the Value in Healthcare Initiative—Transforming Cardiovascular Care.⁶

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The Value in Healthcare Initiative held its kickoff meeting in September 2018, which was attended by representatives from the clinician community, payers, pharmaceutical, device, and technology companies, government agencies, and, importantly, patients. Patient input has been central throughout this process: one patient serves as a member of the Initiative's Executive Committee, and a Patient Advisory Group comprised of 12 AHA Patient Ambassadors serve as ongoing advisors to the initiative.

Based on this meeting's deliberations along with project leadership and the Executive Committee, 4 general areas of focus for the Initiative were determined and working groups were established for each:

- Value-Based Models Learning Collaborative: Implementing value-based payment models for cardiovascular drugs, devices, and care to incent appropriate use of both existing and innovative treatments and products;
- Partnering with Regulators Learning Collaborative: Working with regulatory bodies to offer new clinical trial methods and designs that support a more efficient model of cardiovascular innovation and ready the system for product uptake;
- Predict and Prevent Learning Collaborative: Shifting the health system focus to upstream prevention via implementation science best practices; and
- Prior Authorization Learning Collaborative: Transforming the prior authorization process to facilitate value-based care and better support the matching of patients with appropriate therapies.

Each Learning Collaborative developed a scoping document containing 3 to 5 descriptions of actionable topics. With guidance from leaders on the Initiative's Executive Committee,⁷ the Learning Collaboratives worked together virtually and in person throughout 2019 to refine the scope of their work, and eventually selected a finalized scope of one actionable, specific topic. Each Learning Collaborative met in person in Washington, DC over the summer and early fall of 2019. The deliverables from these groups are being disseminated along with this article in 4 stand-alone articles⁸⁻¹¹; their publication will initiate further work to test and evaluate each of these areas of reform (Table). This article will provide an overview of the initiative's findings and highlight key cross-cutting themes for consideration as the initiative moves forward.

DEFINING VALUE

The first step in the initiative's activities was to define value. Typically, value is defined as outcomes of care divided by the costs of providing that care. However, a key focus of the initiative's work has been keeping the patient perspective central throughout the process, and as such, members of the initiative felt that

the working definition of value should be based on patients' perspectives of value.

To learn how patients define value, the patient advisory group conceptualized, designed, and assisted in implementing a Patient Perspective of Value survey that was disseminated nationally and aimed to assess cardiovascular and stroke patients' perceptions of the value of healthcare. The survey was fielded online in November 2018, and yielded 771 respondents, all of whom were individuals (or their caregivers, responding on their behalf) who had been diagnosed with a cardiovascular or stroke condition. The survey results are described elsewhere, but briefly, respondents ranked having knowledgeable and competent practitioners as providing the most value when asked to define value as it applied to their healthcare experience.¹² Having a clear treatment plan, having timely access to care, and financial affordability were the next leading factors. When patients were asked to consider which factors were most important in assessing the value of their own past healthcare visits, communication and trust were ranked the highest on average.

Based on these results, the committee conceptualized value for the purposes of this initiative as consisting of 5 components: quality, communication, whole-person care, access, and affordability (Figure 1). This 5-component framework was used to represent the concept of value to the Learning Collaborative participants and incorporated into their work. It was reinforced through patient participation in the Learning Collaborative meetings.

VALUE-BASED MODELS LEARNING COLLABORATIVE

Background

The Value-Based Models Collaborative elected to focus on heart failure because the clinical and financial burden of this condition is high and rising. Heart failure is the leading cause of hospitalization among the elderly and its costs are projected to reach \$70 billion by 2030. Under current fee-for-service payment systems, heart failure care can be fragmented, uncoordinated, and of low quality. While there are payment models currently in use by the Centers for Medicare and Medicaid Services and others for episodic care (eg, the Bundled Payments for Care Improvement Initiative) and for primary care (eg, Comprehensive Primary Care), there are no current longitudinal payment models focused on chronic CVD. Episodic models limit the incentive to invest in systems and care redesign to improve longitudinal outcomes, while primary care-based payment models have not focused on subgroups that might need specialty care for optimal management.

Table. Summary of Value in Healthcare Initiative's Learning Collaboratives

Learning Collaborative	Narrowed Focus of Work	Deliverable and Key Recommendations
Value-Based Models	Improve the value of heart failure care through the use of VBP models	A value-based model framework for stage C heart failure with a longitudinal focus on disease management and prevention (including an optional track to prevent high-risk stage B pre-HF from progressing to stage C).
		The framework identifies:
		Payment approach
		Care delivery model
		Quality measurement and evaluation
		Patient population
		Triggers for attributing patients to the model
Necessary data sources		
Predict and Prevent	Improve stroke prevention by better prediction, screening, management, and prevention of modifiable upstream risk factors	A practical framework of frontier strategies that can be used with current primary stroke prevention guidelines to improve upstream stroke prevention and stroke equity.
		The framework identifies:
		A program of strategies and tools for population-level prediction, screening, prevention, and management of hypertension and atrial fibrillation.
Partnering With Regulators	Improve the evidence generation process for cardiovascular drugs and devices	Short- and long-term recommendations for improving cardiovascular therapy development and evidence generation through patient-centered research and clinical trials, and stakeholder partnering with regulators.
		Specific recommendations are made to help accomplish:
		Ensuring that trial participation is convenient and trial outcomes are meaningful to patients.
		Standardizing cardiovascular real-world data from technology, wearables, and artificial intelligence for assessing cardiovascular therapies.
		Improving collaboration between regulators and payers in trial design to streamline and standardize efficient and innovative trials.
Prior Authorization	Improve the prior authorization system for cardiovascular therapies	Innovative solutions to reimagine cardiovascular prior authorization system as more transparent, collaborative, and beneficial to the entire health care ecosystem (clinicians, payers, industry, and patients).
		Approaches for embedding prior authorization into VBP contracts:
		Relaxing/waiving it for population-based VBP models
		Bundling it with episode-based payment models
		Integrating it into VBP models for pharmaceuticals
Strategies for how health care organizations can take great utilization management responsibility and options for streamlining prior authorization processes		

VBP indicates value-based payment.

Deliverable

The Value-Based Models Collaborative identified key components of the value-based model, including target heart failure population, care delivery model, triggers

to enter the model, quality measures of interest, and needed data (Figure 2).⁸

The Value-Based Models Collaborative concluded that an ideal value-based payment model would focus

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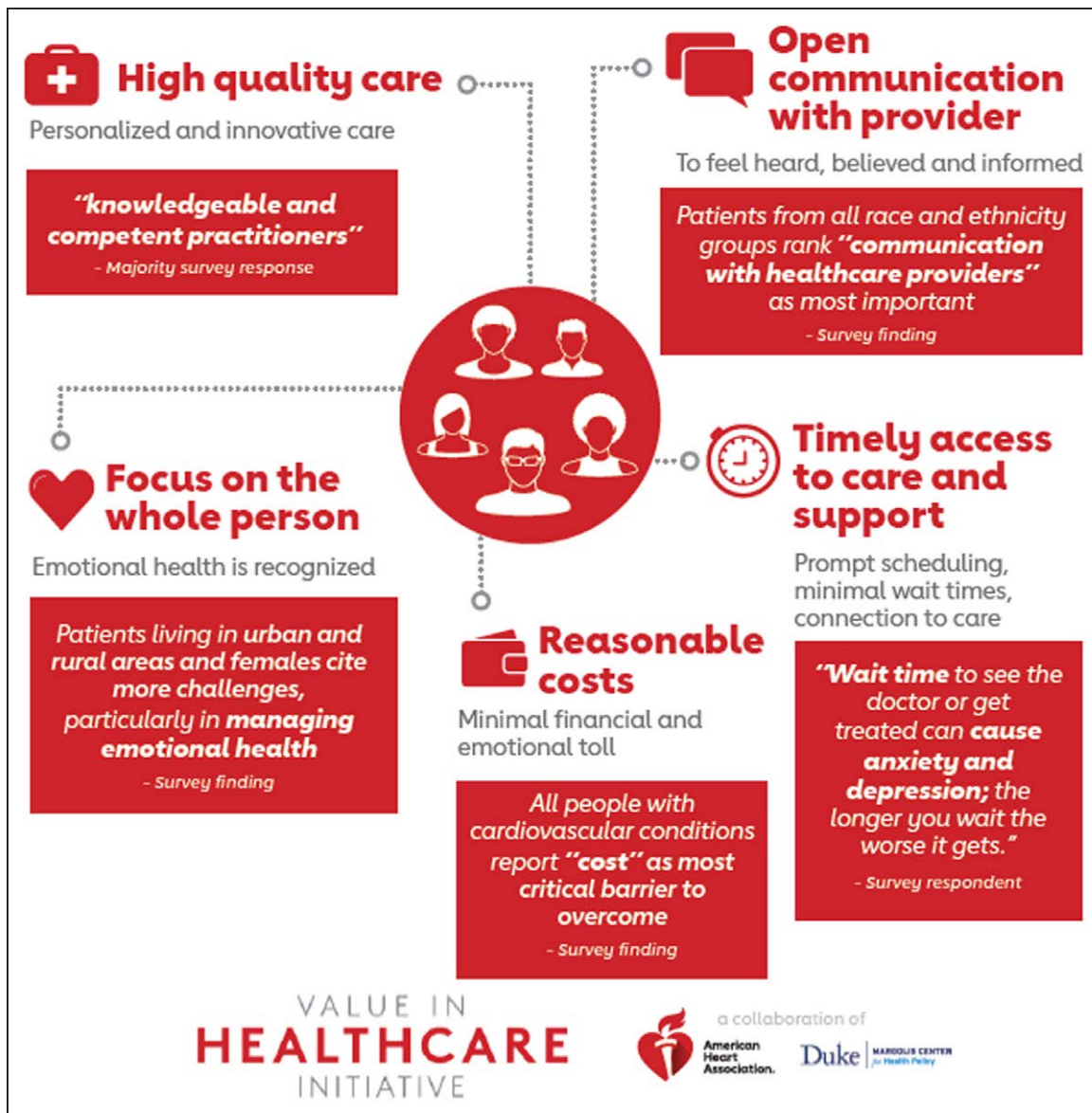


Figure 1. Components of value.

on longitudinal care for patients with chronic heart failure in a population-management model. The primary focus would be preventing adverse events among stage C heart failure patients. Patients would exit the model when their heart failure has progressed to stage D, such as those with ventricular assist devices, transplants, home inotropic therapy, or hospice use. A secondary population (perhaps in an optional track of the model) could include stage B pre-heart failure and focus on prevention of overt clinical heart failure.

Triggers for model entry would include hospitalization or emergency department visits with clinical heart failure. The care team would vary based on local circumstances but generally should be co-led by primary care and general cardiology, using nonphysician providers and all involved team members to their maximum credentialing. The care delivery model should focus on

optimizing guideline-recommended care and improving patient-centered outcomes, including quality of life and mortality. Payment model specifications should support the delivery of high-quality care; for example, a shared-savings approach could be built around relevant patient-centered clinical outcomes as well as provision of best practice, guideline-directed care.

Next Steps

The long-term goal of the Value-Based Models Collaborative is for a pilot payment model focused on high-value care for heart failure to be specified, operationalized, and ultimately implemented. In addition to more fully specifying the above elements, integrating multiple data sources will be necessary to identify the patient population, deliver optimized care, adjust for

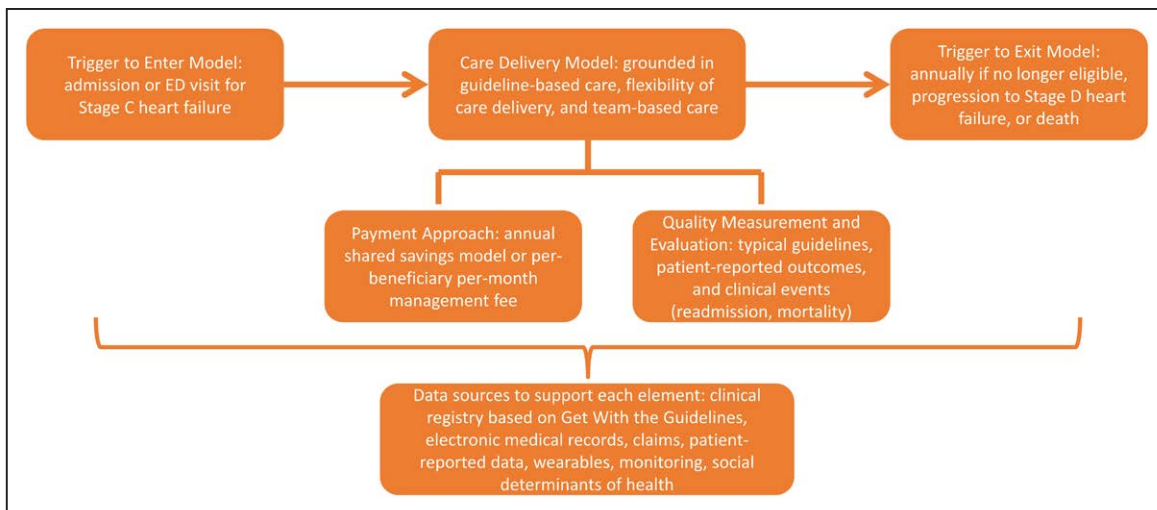


Figure 2. Key components of a value-based payment model.
ED indicates emergency department.

risk, and evaluate the model. Useful data sources could include the Get With The Guidelines–Heart Failure registry, administrative claims data, electronic health record data, patient-reported outcomes data, and data sets with details on social determinants of health. Development of data capability, perhaps as an extension of the existing Get With The Guidelines–Heart Failure program, is a key next step in operationalizing a value-based care delivery model.

PARTNERING WITH REGULATORS LEARNING COLLABORATIVE

Background

The impetus for the Partnering with Regulators Learning Collaborative grew from the recognition that investments in new cardiovascular therapeutics have lagged recently, and the belief that better partnerships could improve this trend. The collaborative identified 3 key issues: (1) complicated, costly, and slow development and approval processes; (2) low return on recent investment relative to other disease states^{6,13}; in part due to (3) slow uptake and implementation of new therapies because of issues with payer coverage and pricing.^{14,15} The Partnering with Regulators Collaborative agreed that these problems stem in part from an outdated ecosystem for cardiovascular therapy development and approval. To speed the process, reduce complexity and cost, and improve the quality of the evidence gathered, multifaceted improvements should be made. Transitioning to digital methods of data collection, trial administration, and patient recruitment could enable the use of real-world evidence to improve clinical trials.^{16,17} In addition, the Food and Drug Administration's Real World Evidence initiative focuses on evaluating the fitness-for-use of existing data from real-world popula-

tions for regulatory decision making. The application of technology to recruit and monitor patients could reduce cost and increase power by allowing clinical research to be performed more efficiently.¹⁸



Deliverable

The Partnering with Regulators Collaborative identified a series of short-term actions to improve the process of cardiovascular therapy development, clinical trials, regulatory approval, and use of real-world data and evidence.¹⁰ They also identified long-term strategies to address systemic barriers to patient engagement and centrality in therapy development. Although patients have been under-involved in guiding and supporting cardiovascular clinical research and trial recruitment, their increased participation could rejuvenate the research enterprise.¹⁹ Increasingly diverse recruitment would improve the generalizability of evidence.²⁰ Ensuring that outcomes used as end points are meaningful to patients would help to establish a more collaborative and inclusive research and development process. Patient involvement in clinical trial design and end point evaluation would improve the meaningfulness of the generated evidence and facilitate uptake by clinicians and health systems.^{21,22} The report also discusses the need to expand the research community network and recognize those systems and hospitals that have made a commitment to cardiovascular trials. Lastly, standards for the collection and analysis of real-world and commercial device application data acceptable for use in cardiovascular trials are needed.

Next Steps

One key recommendation of the report is for the AHA to develop a regular convening for industry, research-

ers, and other stakeholders in the cardiovascular therapy pipeline ecosystem to meet with the Food and Drug Administration and other regulators affecting research or implementation (eg, National Institutes of Health, Centers for Medicare and Medicaid Services). This would focus on barriers to innovation, ideas for innovative design, and would not be specific to a particular therapy application.

PREDICT AND PREVENT LEARNING COLLABORATIVE

Background

The Predict and Prevent Learning Collaborative's premise is that value could be improved by shifting the health system focus to upstream prevention rather than treatment of extant disease. With improved prediction models, prevention could potentially be more effectively targeted to improve long-term cardiovascular outcomes. The collaborative focused on stroke prevention by prediction, prevention, and management of hypertension and atrial fibrillation—2 upstream risk factors with evidence-based strategies that could be implemented in diverse settings. Stroke is the fifth leading cause of death in the United States,²³ and despite treatment advances, stroke mortality has stalled or risen for some subpopulations the last several years.²⁴ Further, the burden of stroke is disproportionately borne by racial and ethnic minorities, who face persistent inequalities in stroke prevention, care, and outcomes.²⁵ Identifying opportunities to better implement stroke prediction and prevention strategies is critical to reverse this trend.

Deliverable

The Predict and Prevent Collaborative conceptualized a resource kit to improve stroke prevention and equity by identifying, modifying, and managing upstream medical risk factors, in particular, hypertension and atrial fibrillation. The toolkit synthesized 2 key areas of knowledge that are laid out in the Predict and Prevent Collaborative article.⁹ First, the possible key components of an upstream stroke prediction and prevention program focused on hypertension and atrial fibrillation, with a focus on strategies that are likely to be feasible in a wide variety of settings. Second, the toolkit identified potential barriers to implementation in clinical practice (eg, regulatory and policy challenges, risk communication, low resource settings, local context, technological constraints, medication adherence), and strategies to overcome them.

The stroke prevention resource kit fits well within the overall Value in Healthcare Initiative patient-centered value framework, as it ties together the provision of high-quality care, communication, whole-

person care, access, and costs. Patients receiving team-based management of stroke risk factors would be receiving guideline-concordant care through a high-fidelity program. Communication and whole-person care would be facilitated by the team-based approach, and access could be improved through the use of remote monitoring and other technologies. Finally, costs are generally low for preventive interventions, which could be cost-effective if events are avoided downstream.

Next Steps

A goal of the resource kit is to provide enough detail on key strategies without being overly prescriptive—to balance scalability and customization—and is designed to be implemented in low-resource settings and to benefit vulnerable populations. The Predict and Prevent Collaborative hopes to identify possible partners to pilot test such a toolkit in the immediate future.

PRIOR AUTHORIZATION LEARNING COLLABORATIVE



Background

Prior authorization is the most well known of the utilization management tools that payers use to help ensure appropriate healthcare provision and control costs. It compels clinicians to communicate the presence of specific clinical attributes to payers in order for therapeutics and testing to be approved and financially covered and is primarily instituted for expensive novel therapeutics and testing. Consensus among payers is that utilization management protocols such as prior authorization are necessary, even though opportunities remain to improve their functionality and administration. The need for constraints on clinician testing and treatment selections are explained by evidence of ongoing low-value care choices as well as prices that are not aligned with value.^{26,27} Potential mechanisms to improve utilization management include waiving prior authorization for high-performing clinicians, more fully automating prior authorization processes, and implementing standards for payer and clinician communications. Increasing participation in value-based contracting may serve as the mechanism to strategically coordinate clinicians, health systems, and payers. In these models, utilization management can be integrated into clinical care as part of broader value-based interventions to improve patient health outcomes.²⁸

Deliverable

The Prior Authorization Collaborative produced a guide for stakeholders to improve deployment of prior autho-

rization, including within value-based contracts.¹¹ This playbook contains strategies to increase predictability, limit bureaucratic burden, and improve patient access and the patient-clinician experience. Strategies to streamline prior authorization include improved digital communications and data interoperability, audit-based or automated programs to expedite approvals, as well as enhanced transparency and nondenial models (in which a payer automatically escalates requests that would traditionally be denied to peer-to-peer discussions). The benefits and drawbacks of these methods will need to be individualized by the specific involved stakeholders. The deliverable highlighted examples of these principles in the real world, including cardiovascular examples when found.

Next Steps

This concept may coalesce around future AHA-mediated roundtable discussions with payers, clinicians, patients, and health systems to establish the appropriate guide rails for these activities. These discussions may also allow development of use criteria for pharmaceutical prescription and clinical testing that can guide utilization management, particularly if they can be produced more rapidly than the current guideline generation process, with the ability to respond more nimbly to the constantly changing evidence base.

CROSS-CUTTING THEMES

A number of cross-cutting themes emerged across the Learning Collaboratives. These themes represent areas where broader investment or advocacy may facilitate multiple avenues towards value.

Patient Voice

Each of the Learning Collaboratives identified the need to better incorporate patient perspectives into problem-solving deliberations and assessments of value. As the principle consumers of healthcare, patients deserve a strong voice in identifying concerns, determining their importance, and formulating their solutions. However, patient perspectives have not been routinely integrated into decision-making around end point selection and value assessment in the healthcare ecosystem.²⁹

The patient voice should also be heard as a clinical outcome. The Partnering with Regulators Collaborative noted that clinical trials created by academia, industry, and regulators frequently do not include patient quality of life and preference ascertainment.³⁰ The Value-Based Models Collaborative noted that including patient-reported outcomes in payment models should be encouraged to incent clinicians to focus on

these important measures. Inherently, patient-reported outcome measures are patient-centered, as patients populate them, and they capture distinct aspects of the patient experience from other clinical and physiological assessments.³¹ Patient-reported outcomes can answer crucial patient-centered questions about whether they will feel better, how their symptoms and well-being will change over time, and the overall value of an intervention.³² The relative importance and disutility of cardiovascular treatments for patients should inform all projects intended to improve value, and these can only be known by listening to patients.³³

Equity

Another key cross-cutting theme was health equity. There are myriad examples of inequities in CVD care and outcomes and improving them was noted as an important need across the collaboratives. The lack of equity is reflected in a shorter life expectancy, poorer health outcomes, higher rates of disease, and lack of access to care.³⁴ In the United States, minorities and indigenous peoples, as well as those living in rural areas, suffer the greatest inequities.^{35,36}

In the Value-Based Models Collaborative, there was agreement that team-based, patient-centered care would by necessity include attention to social determinants of health, since addressing these issues is critical to achieving good clinical outcomes. A more flexible payment model could incent practices to invest in services, such as social work, or partnerships with community-based organizations, that could benefit their most vulnerable patients. In the Predict and Prevent Collaborative, there a focus on prevention, which is often most underused in underserved groups where the burden of stroke is also higher. Thus a focus on prevention could improve equity. There is also a need for strategies that are customizable at the local level given varying resources and unique needs within at-risk populations. In the Prior Authorization Collaborative, recent data was cited demonstrating that many utilization review procedures disproportionately hurt racial and ethnic minorities and individuals living in poverty; therefore, improving these processes could improve equity.

Based on the conversations of Learning Collaborative participants, the need to understand and address the unique health needs of persons residing in rural America was identified as an additional priority area. It is imperative that all populations, including those living in rural areas, benefit from innovations in care models that a value-based system may bring. This prompted the publication of Call to Action: Rural Health: A Presidential Advisory by the AHA and American Stroke Association in February 2020.³⁷

Digital Tools, Wearables, and Patient-Generated Data

Across Collaboratives, it was recognized that improving the value of cardiovascular care will require us to reimagine what cardiovascular care looks like. Towards this new paradigm for care, digital tools, wearables, and remote monitoring devices represent infrastructure that may be vital to developing novel care pathways and driving high-value care.

For example, the Apple watch may be able to identify patients at risk for thromboembolic events related to undiagnosed atrial fibrillation—an advance that could make the goals outlined in the Predict and Prevent Collaborative more easily achievable if scaled and deployed with appropriate quality control. Similarly, using the AliveCor platform to get a medical-grade ECG in 30 seconds, or the Butterfly iQ to democratize echocardiography and ultrasound could make preventive care more targeted and accessible, or could facilitate data collection for clinical trials, relevant to the Partnering with Regulators Collaborative. Using an implantable pulmonary artery pressure sensor to optimize care for selected high-risk patients with heart failure could be of particular relevance to the Value-Based Models Collaborative's proposed new payment model for this group. If such interventions significantly reduce hospitalizations and improve quality of life, they could be high-value even if they are relatively high-cost.

While we are early in our application of these novel tools, their potential to improve quality and value is provocative, particularly if they are deployed in a manner cognizant of disparities and resources. Looking ahead, the application of implanted sensors, health apps, and digital tools may become a cornerstone for improving the value of care, if used appropriately and targeted carefully. Relatedly, the importance of engaging patients to generate, curate, share, and leverage their own data will be critical. On the contrary, if such technologies are deployed without attention to costs, disparities, and access, they could worsen value. There will need to be further collaborations between technology and device companies, entrepreneurs, investigators, and most importantly patients, to identify particularly promising areas for development.

Flexible Value-Based or Alternative Payment Models

Another cross-cutting theme in each of the collaboratives was the idea that flexible payment models are needed to facilitate the type of innovation and change for which each group advocated.

Currently, most outpatient care is delivered within a fee-for-service construct, in which typical medical services like physician visits and imaging tests are reimbursed,

while things like care coordination, social work, coaching, and monitoring are not. However flexible payment models, as are used in many value-based and alternative payment programs, allow provision of needed services and the hiring of key personnel that may not have been reimbursed under fee-for-service. For example, cardiovascular care involves significant care coordination, and which many current alternative payment models, such as accountable care organizations and bundled payment programs, explicitly incentivize. This can incentivize the involvement of care coordinators, community health workers, patient navigators, and other team members in patient management.

Flexible value-based or alternative payment models also allow payment to be explicitly linked to guideline adherence and quality performance, which is not possible under standard fee-for-service. Where inadequate delivery of quality care exists, financial incentives can create a powerful nudge to clinicians, administrators, and care team members to focus on improving performance in key areas. On the contrary, potential unintended consequences of such programs should be considered and monitored. For example, linking payment to guideline adherence may result in inappropriate application of the guidelines or gaming of the system; appropriate monitoring would be necessary to limit any unintended consequences.

Flexible value-based or alternative payment models were central to all the Collaboratives. The Value-Based Models Collaborative focused on this as their central theme, but the Prior Authorization Collaborative also included payment models as a way to improve patients' access to medications. The Predict and Prevent Collaborative included supportive payment models as a key implementation consideration for getting risk factor modification into practice. For the Partnering with Regulators Collaborative, flexible payment models could be used to speed uptake of new therapeutics where appropriate, or to encourage de-prescription of old ones. Across the collaboratives, payment models are a key tool to reshape value in cardiovascular care delivery.

Data Standards and Interoperability

Issues of data standards and interoperability were important across collaboratives as well. For example, healthcare data are collected in a large and growing number of settings, both within and outside of the care delivery environment. Given the widespread interest in using real-world data from electronic health records, administrative claims, wearables, and online portals, the ability to aggregate information from distinct environments is an increasingly central component of health care delivery and large-scale population health research, and as such is important across many of the Collaboratives.

Over the past decade, major progress has been made to enable interoperability through publication of consensus-based standards, such as the Fast Healthcare Interoperability Resources standard. However, ability to customize standards can result in inconsistencies due to different local implementation, which can challenge multi-system approaches. Even in the setting of optimal interoperability, there are limited incentives for health-care providers to share data. Providing meaningful incentives to providers and healthcare systems is particularly important given growing concerns about data privacy and potential risk for re-identification.

These issues have direct relevance to collaborative efforts. For example, data sources relevant to prediction and prevention research often span clinical and behavioral factors, which present unique challenges to investigators due to inherently limited data interoperability across sources. Value-based models require integration of data from clinical and financial databases, as well as potentially from patient wearables and other devices. Streamlining regulatory processes using real-world data generation is impossible without interoperability, as would be any revolutionary changes to prior authorization.

The ability to share and use data to improve patient care is increasingly recognized as a critical component to realizing the potential of real-world data for value, risk prediction, regulatory uses, and rational approaches to pharmaceutical policy such as prior authorization. Uniting stakeholders across healthcare systems, informatics research communities, data privacy experts, and patient communities will be critical to continuing progress toward this goal.

Implementation Science

Finally, the field of implementation science, the study of methods and strategies to promote the uptake of evidence-based practices into routine clinical usage,^{38,39} has cross-cutting relevance to the work of each of the collaboratives. Implementation science aims to address gaps in how health care is delivered, and therefore, is a crucial piece in moving value to the bedside. It is well known that effective therapy may still not reach the target population. For example, while the effectiveness of controlling hypertension is well known, the ability to provide this therapy on a population basis remains inadequate.^{40,41}

Implementation science evaluates which approaches work, which do not, and why. Such work is central for value-based payment models and clinical prevention strategies to maximize successes and minimize unintended consequences. For example, studying various implementation strategies for remote monitoring can determine which are most likely to drive improvements in care for heart failure patients in value-based payment

models. It can also inform ways in which interventions can be most effective in providing care for vulnerable populations. Implementation studies might find that successful interventions for heart failure management must involve cultural awareness, to meet with and work with communities where they are sociologically and economically. Or such studies might demonstrate that successful interventions for prevention of stroke involve communities taking ownership of the process, where the members of the community are aware that the program being offered is in their interest and are prepared to champion it.³⁸ Implementation science, therefore, offers approaches which will be critical to improving medical care and public health, crucial to success across each collaborative.

CONCLUSIONS

The Value in Healthcare Initiative brought together a diverse group of stakeholders to think deeply about how to improve value across the care delivery, with a particular focus on achieving value that matters to patients. Each collaborative has produced a deliverable article, elsewhere in this journal^{8–11} that aims to spur meaningful change and to move cardiovascular care towards providing higher value to all its constituents. The AHA is committed to seeing the recommendations from the initiative's work put into action and calls on organizations across, as well as outside, the healthcare ecosystem to implement and pilot the recommendations.

Additionally, the Association plans to:

- Incorporate the learnings of this work across existing AHA programs, as well as use them to inform future work
- Continue to facilitate convenings of the nation's top researchers, regulators, and innovators and catalyze activity in support of the initiative's aims
- Foster further dialogue among the AHA science and research community to support research and analysis that informs the topics, including conducting implementation science
- Engage in policy in line with the recommendations of the initiative and support more patient-centered care and eliminate barriers to the receipt of evidence-based, appropriate care by patients
- Leverage the association's varied and diverse communication and dissemination channels to showcase best practices and nontraditional approaches.

ARTICLE INFORMATION

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REFERENCES

- Buttar HS, Li T, Ravi N. Prevention of cardiovascular diseases: role of exercise, dietary interventions, obesity and smoking cessation. *Exp Clin Cardiol.* 2005;10:229–249.
- U.S. Department of Health & Human Services. Poverty. Office of Disease Prevention and Health Promotion. 2019. Available at: <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-health/interventions-resources/poverty#7>. Accessed January 20, 2020.
- Qato DM, Lindau ST, Conti RM, Schumm LP, Alexander GC. Racial and ethnic disparities in cardiovascular medication use among older adults in the United States. *Pharmacoepidemiol Drug Saf.* 2010;19:834–842. doi: 10.1002/pds.1974
- Mensah GA, Wei GS, Sorlie PD, Fine LJ, Rosenberg Y, Kaufmann PG, Mussolino ME, Hsu LL, Addou E, Engelgau MM, Gordon D. Decline in cardiovascular mortality: possible causes and implications. *Circ Res.* 2017;120:366–380. doi: 10.1161/CIRCRESAHA.116.309115
- Van Norman GA. Overcoming the declining trends in innovation and investment in cardiovascular therapeutics: beyond EROOM's law. *JACC Basic Transl Sci.* 2017;2:613–625. doi: 10.1016/j.jacbs.2017.09.002
- McClellan M, Brown N, Califf RM, Warner JJ. Call to action: urgent challenges in cardiovascular disease: a presidential advisory from the American Heart Association. *Circulation.* 2019;139:e44–e54. doi: 10.1161/CIR.0000000000000652
- American Heart Association. Our Leadership: Value in Healthcare Initiative. American Heart Association. 2020. Available at: <https://www.heart.org/en/about-us/value-in-healthcare-initiative/our-leadership-and-participants>. Accessed May 20, 2020.
- Joynt Maddox K, Bleser WK, Crook HL, Nelson AJ, Hamilton Lopez M, Saunders RS, McClellan MB, Brown N; American Heart Association Value-

- Based Models Learning Collaborative. Advancing value-based models for heart failure: a call to action from the value in healthcare initiative's value-based models learning collaborative. *Circ Cardiovasc Qual Outcomes.* 2020;13:e006483. doi: 10.1161/CIRCOUTCOMES.120.006483
- Buflino VJ, Bleser WK, Singletary EA, Granger BB, O'Brien EC, Elkind MSV, Hamilton Lopez M, Saunders RS, McClellan MB, Brown N, the American Heart Association Predict & Prevent Learning Collaborative. Frontiers of upstream stroke prevention and reduced stroke inequity through predicting, preventing, and managing hypertension and atrial fibrillation: a call to action from the value in healthcare initiative's predict & prevent learning collaborative. *Circ Cardiovasc Qual Outcomes.* 2020;13:e006780. doi: 10.1161/CIRCOUTCOMES.120.006780
- Warner JJ, Bleser WK, Crook HL, Whelan KM, Roiland RA, Hamilton Lopez M, Saunders RS, Wang TY, Hernandez AF, McClellan MB, Califf RM, Brown N, the American Heart Association Partnering with Regulators Learning Collaborative. Improving cardiovascular drug and device development and evidence through patient-centered research and Clinical Trials: a call to action from the value in healthcare initiative's partnering with regulators learning collaborative. *Circ Cardiovasc Qual Outcomes.* 2020;13:e006606. doi: 10.1161/CIRCOUTCOMES.120.006606
- Psotka MA, Singletary EA, Bleser WK, Roiland RA, Hamilton Lopez M, Saunders RS, Wang TY, McClellan MB, Brown N, the American Heart Association Prior Authorization Learning Collaborative. Streamlining and reimaging prior authorization under value-based contracts: a call to action from the value in healthcare initiative's prior authorization learning collaborative. *Circ Cardiovasc Qual Outcomes.* 2020;13:e006564. doi: 10.1161/CIRCOUTCOMES.120.006564
- Huang K, Konig M, Psotka MA, Wadhwa RK, JoyntMaddox KE. Cardiovascular patient perspectives on value in the healthcare experience. *Cardiovasc Qual Outcomes.* 2020;13:e006617. doi: 10.1161/CIRCOUTCOMES.120.006617
- O'Connor CM, Psotka MA, Fiuzat M, Lindenfeld J, Abraham WT, Bristow MR, Canos D, Harrington RA, Hillebrandner M, Jessup M, Malik FI, Solomon SD, Stockbridge N, Tchong JE, Unger EF, Whellan DJ, Zuckerman B, Califf RM. Improving heart failure therapeutics development in the United States: the heart failure collaborative. *J Am Coll Cardiol.* 2018;71:443–453. doi: 10.1016/j.jacc.2017.11.048
- Cohen R, Boersma P, Vahratian A. Strategies used by adults aged 18–64 to reduce their prescription drug costs, 2017. 2019. Available at: <https://www.cdc.gov/nchs/data/databriefs/db333-h.pdf>. Accessed January 20, 2020.
- Persaud N, Bedard M, Boozary AS, Glazier RH, Gomes T, Hwang SW, Jüni P, Law MR, Mamdani MM, Manns BJ, Martin D, Morgan SG, Oh PI, Pinto AD, Shah BR, Sullivan F, Umali N, Thorpe KE, Tu K, Laupacis A, Carefully Selected and Easily Accessible at No Charge Medicines (CLEAN Meds) Study Team. Effect on treatment adherence of distributing essential medicines at no charge: the CLEAN Meds Randomized Clinical Trial. *JAMA Intern Med.* 2020;180:27–34. doi: 10.1001/jamainternmed.2019.4472
- McConnell MV, Shcherbina A, Pavlovic A, Homburger JR, Goldfeder RL, Waggot D, Cho MK, Rosenberger ME, Haskell WL, Myers J, Champagne MA, Mignot E, Landray M, Tarassenko L, Harrington RA, Yeung AC, Ashley EA. Feasibility of obtaining measures of lifestyle from a smartphone app: the MyHeart Counts Cardiovascular Health Study. *JAMA Cardiol.* 2017;2:67–76. doi: 10.1001/jamacardio.2016.4395
- Greenwood S, Perrin A, Duggan M. Social Media Updated 2016. 2016. Pew Research Center; Available at: <https://www.pewresearch.org/internet/2016/11/11/social-media-update-2016/>. Accessed December 18, 2020.
- Lauer MS, D'Agostino RB Sr. The randomized registry trial—the next disruptive technology in clinical research? *N Engl J Med.* 2013;369:1579–1581. doi: 10.1056/NEJMp1310102
- The Center for Information and Study on Clinical Research Participation. Report on The Participation Decision-Making Process. Available at: <https://www.ciscrp.org/wp-content/uploads/2019/06/2017-CISCRP-Perceptions-and-Insights-Study-Decision-Making-Process.pdf>. Accessed October 14, 2019.
- Scott PE, Unger EF, Jenkins MR, Southworth MR, McDowell TY, Geller RJ, Elahi M, Temple RJ, Woodcock J. Participation of women in clinical trials supporting FDA approval of cardiovascular drugs. *J Am Coll Cardiol.* 2018;71:1960–1969. doi: 10.1016/j.jacc.2018.02.070
- Chow RD, Wankhedkar KP, Mete M. Patients' preferences for selection of endpoints in cardiovascular clinical trials. *J Community Hosp Intern Med Perspect.* 2014;4. doi: 10.3402/jchimp.v4.22643
- Chalasan M, Vaidya P, Mullin T. Enhancing the incorporation of the patient's voice in drug development and evaluation. *Res Involv Engagem.* 2018;4:10. doi: 10.1186/s40900-018-0093-3

23. Centers for Disease Control and Prevention. Stroke. US Department of Health and Human Services; 2019. Available at: <https://www.cdc.gov/stroke/index.htm>. Accessed October 14, 2019.
24. Yang Q, Tong X, Schieb L, Vaughan A, Gillespie C, Wiltz J, Coleman King S, Odom E, Merritt R, Hong Y, George M. Vital signs: recent trends in stroke death rates — United States, 2000–2015. *MMWR Morb Mortal Wkly Rep*. 2017;66:933–939. doi: 10.15585/mmwr.mm6635e1
25. Qian F, Fonarow GC, Smith EE, Xian Y, Pan W, Hannan EL, Shaw BA, Glance LG, Peterson ED, Eapen ZJ, Hernandez AF, Schwamm LH, Bhatt DL. Racial and ethnic differences in outcomes in older patients with acute ischemic stroke. *Circ Cardiovasc Qual Outcomes*. 2013;6:284–292. doi: 10.1161/CIRCOUTCOMES.113.000211
26. Shrank WH, Rogstad TL, Parekh N. Waste in the US health care system: estimated costs and potential for savings. *JAMA*. 2019;322:1501–1509. doi: 10.1001/jama.2019.13978
27. Campbell JD, Belozeroff V, Whittington MD, Rubin RJ, Raggi P, Briggs AH. Prices for common cardiovascular drugs in the US are not consistently aligned with value. *Health Aff (Millwood)*. 2018;37:1298–1305. doi: 10.1377/hlthaff.2018.0221
28. Blesar WK, Saunders RS, Muhlestein DB, Morrison SQ, Pham HH, McClellan MB. ACO quality over time: the MSSP experience and opportunities for system-wide improvement. *Am J Accountable Care*. 2018;6:e1–e15.
29. Khazanie P, Krumholz HM, Kiefe CI, Kressin NR, Wells B, Wang TY, Peterson ED. Priorities for cardiovascular outcomes research: a report of the national heart, lung, and blood institute's centers for Cardiovascular Outcomes Research Working Group. *Circ Cardiovasc Qual Outcomes*. 2017;10:e001967. doi: 10.1161/CIRCOUTCOMES.115.001967
30. Rahimi K, Malhotra A, Banning AP, Jenkinson C. Outcome selection and role of patient reported outcomes in contemporary cardiovascular trials: systematic review. *BMJ*. 2010;341:c5707. doi: 10.1136/bmj.c5707
31. Psotka MA, von Maltzahn R, Anatchkova M, Agodoa I, Chau D, Malik FI, Patrick DL, Spertus JA, Wiklund I, Teerlink JR. Patient-reported outcomes in chronic heart failure: applicability for regulatory approval. *JACC Heart Fail*. 2016;4:791–804. doi: 10.1016/j.jchf.2016.04.010
32. Kosiborod M, Soto GE, Jones PG, Krumholz HM, Weintraub WS, Deedwania P, Spertus JA. Identifying heart failure patients at high risk for near-term cardiovascular events with serial health status assessments. *Circulation*. 2007;115:1975–1981. doi: 10.1161/CIRCULATIONAHA.106.670901
33. Fontana M, Asaria P, Moraldo M, Finegold J, Hassanally K, Manisty CH, Francis DP. Patient-accessible tool for shared decision making in cardiovascular primary prevention: balancing longevity benefits against medication disutility. *Circulation*. 2014;129:2539–2546. doi: 10.1161/CIRCULATIONAHA.113.007595
34. Havranek Edward P, Mujahid Mahasin S, Barr Donald A, Blair Irene V, Cohen Meryl S, Cruz-Flores S, Davey-Smith G, Dennison-Himmelfarb Cheryl R, Lauer Michael S, Lockwood Debra W, Rosal M, Yancy Clyde W. Social determinants of risk and outcomes for cardiovascular disease. *Circulation*. 2015;132:873–898. doi: 10.1161/CIR.0000000000000228
35. Economic Policy Institute. The State of Working America Key Numbers: Poverty. 2019. Available at: <http://stateofworkingamerica.org/fact-sheets/poverty/>. Accessed October 20, 2019.
36. National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division, Board on Population Health and Public Health Practice and Committee on Community-Based Solutions to Promote Health Equity in the United States. *Communities in Action: Pathways to Health Equity*. Washington, DC: National Academies Press; 2017.
37. Harrington RA, Califf RM, Balamurugan A, Brown N, Benjamin RM, Braund WE, Hipp J, Konig M, Sanchez E, Joynt Maddox KE. Call to action: rural health: a presidential advisory from the American Heart Association and American Stroke Association. *Circulation*. 2020;141:e615–e644. doi: 10.1161/CIR.0000000000000753
38. Handley MA, Gorukanti A, Cattamanchi A. Strategies for implementing implementation science: a methodological overview. *Emerg Med J*. 2016;33:660–664. doi: 10.1136/emermed-2015-205461
39. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. *BMC Psychol*. 2015;3:32. doi: 10.1186/s40359-015-0089-9
40. Ferdinand KC, Yadav K, Nasser SA, Clayton-Jeter HD, Lewin J, Cryer DR, Senatore FF. Disparities in hypertension and cardiovascular disease in blacks: the critical role of medication adherence. *J Clin Hypertens (Greenwich)*. 2017;19:1015–1024. doi: 10.1111/jch.13089
41. Valderrama AL, Gillespie C, Mercado C. Racial/Ethnic disparities in the awareness, treatment, and control of hypertension — United States, 2003–2010. *MMWR Morb Mortal Wkly Rep*. 2013;62:351–355.

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