

# The Learning Healthcare System and Cardiovascular Care

## A Scientific Statement From the American Heart Association

**ABSTRACT:** The learning healthcare system uses health information technology and the health data infrastructure to apply scientific evidence at the point of clinical care while simultaneously collecting insights from that care to promote innovation in optimal healthcare delivery and to fuel new scientific discovery. To achieve these goals, the learning healthcare system requires systematic redesign of the current healthcare system, focusing on 4 major domains: science and informatics, patient-clinician partnerships, incentives, and development of a continuous learning culture. This scientific statement provides an overview of how these learning healthcare system domains can be realized in cardiovascular disease care. Current cardiovascular disease care innovations in informatics, data uses, patient engagement, continuous learning culture, and incentives are profiled. In addition, recommendations for next steps for the development of a learning healthcare system in cardiovascular care are presented.

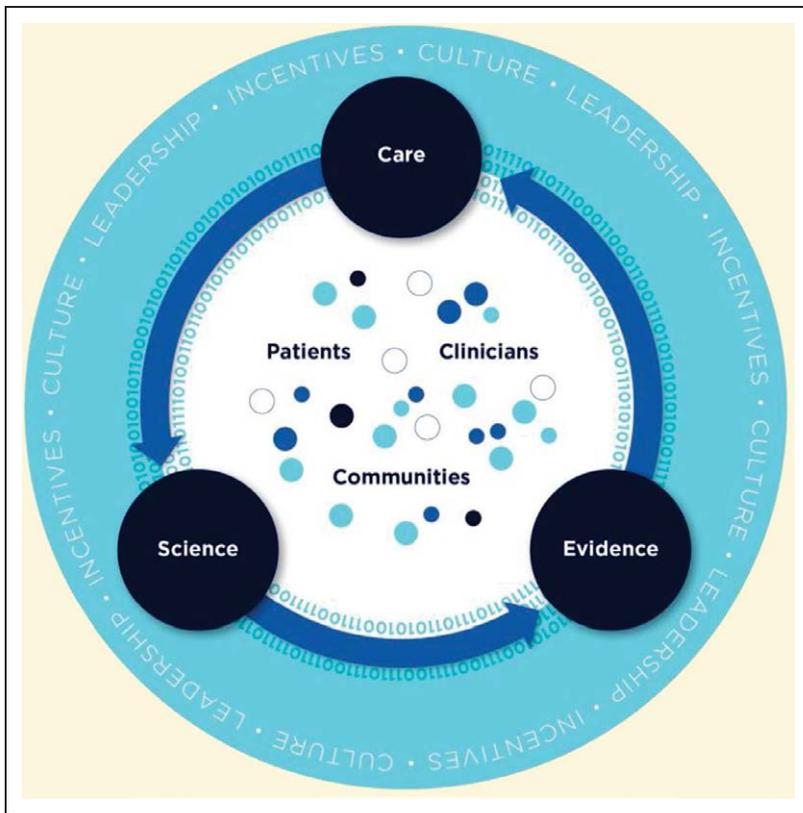
Health care has never been more complex. Clinicians and patients must make decisions that integrate the continually evolving scientific evidence base with hundreds of individual data points such as patients' vital signs, symptoms, comorbidities, medications, test results, and preferences. Furthermore, once these decisions are made, little information is available about their impact, limiting the ability to learn from and ultimately improve care delivery. This inability of the healthcare system to learn from its operation results in significant inefficiencies, substantial costs, and suboptimal health outcomes.

The creation of a learning healthcare system (LHS) can potentially address these issues. The LHS uses health information technology and the health data infrastructure to apply scientific evidence at the point of clinical care while simultaneously collecting insights from that care to promote innovation in optimal healthcare delivery and to fuel new scientific discovery<sup>1,2</sup> (Figure 1). Thus, the LHS enables rapid, iterative learning in which "evidence informs practice, and practice informs evidence."<sup>1</sup> In 2012, the National Academy of Medicine issued a report titled *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*<sup>2</sup> that outlined the rationale and structure for the LHS.<sup>2</sup> The authors argued that recent advances in information processing and connectivity, healthcare organizational design, and reimbursement policies centered on quality rather than quantity of care provided the necessary tools for the creation of the LHS. Accordingly, they called for systematic redesign of the healthcare system, focusing on 4 major domains: science and informatics, patient-clinician partnerships, incentives, and development of a continuous learning culture.

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**Figure 1. Schematic of a learning healthcare system.**

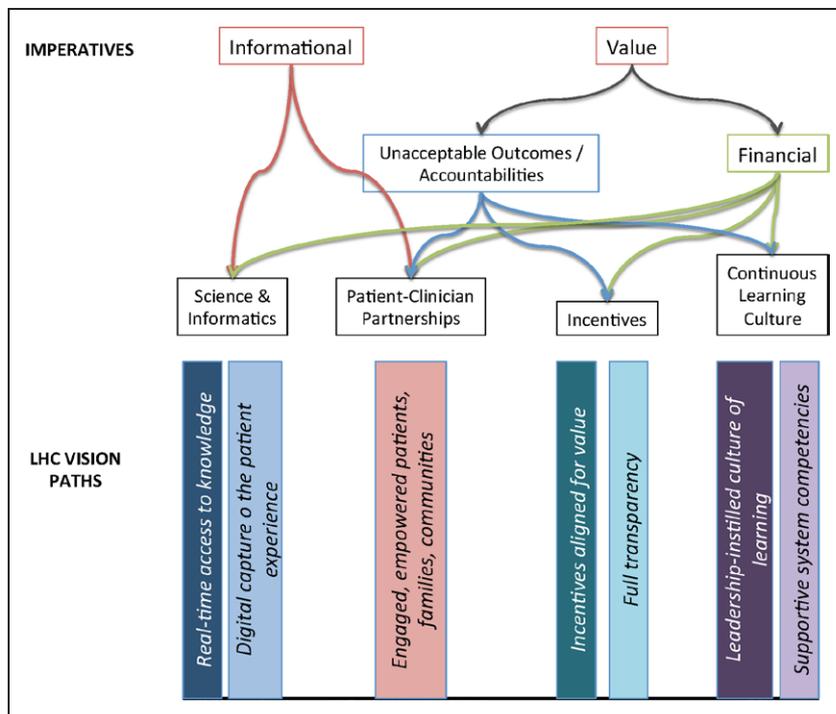
Modified from Figure 5-1, *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*.<sup>2</sup> <https://www.nap.edu/catalog/13444/best-care-at-lower-cost-the-path-to-continuously-learning>. Reprinted with permission from the National Academy of Sciences, courtesy of the National Academies Press, Washington, DC. Copyright © 2013, National Academy of Sciences.

Despite this road map, replacing the current health-care system with the LHS is a massive task. To make this more manageable, one approach is to implement and evaluate the LHS concept in one aspect of clinical medicine, using it as a “learning laboratory” environment in which to refine its concepts. Then, lessons from this experience can be extended to other aspects of medicine. Cardiovascular disease (CVD) care delivery, for a variety of reasons, is well suited to serve as a model for the LHS. First, CVD significantly affects the population: It is a highly prevalent condition, affects all ages and demographic groups, and is associated with significant morbidity and mortality. Second, CVD is a costly disease to manage for both the health system and the patients themselves. Third, CVD care touches on multiple areas of healthcare delivery, including prevention, diagnostics, therapeutic procedures, and chronic disease management. This characteristic of CVD care is especially important because cardiology specialists often coordinate efforts with other providers in prevention and chronic disease management. LHS concepts speak to effective methods of care coordination, and this aspect of CVD care can be informative to those efforts. Fourth, a wealth of scientific evidence to inform clinical CVD care and significant CVD care data collection efforts already exist to inform practice innovation and research. Together, these characteristics of CVD care delivery make the condition an informative model in which to translate LHS concepts into action.

## LHS CONCEPTS AND FRAMEWORK

The need for the LHS definition was motivated by the recognition that 2 imperatives, informational and value, mandate improving healthcare delivery in the United States (Figure 2).<sup>3</sup> The first imperative, informational, arises from the massive amount of clinical information healthcare providers need to manage and the increasing complexity of the current healthcare system and the patients it serves. As a result, these characteristics prevent the effective absorption and application of the right information to the right patient at the right time. The second imperative, value, arises from the recognition that healthcare value, defined as health outcomes achieved per dollar spent, is suboptimal in the current healthcare delivery system.<sup>4</sup> Optimal health outcomes require high-quality care, which is often impeded by incomplete information on both the best evidence and its optimal application to individual patients. Similarly, optimal healthcare costs require efficient healthcare delivery, which is often impeded by duplication of efforts, misaligned incentives, and lack of cost transparency.

To respond to these imperatives, the LHS has 4 major characteristics: effective use of science and informatics to support optimal care delivery, engagement of effective patient-clinician partnerships, alignment of healthcare delivery incentives to support the LHS goals, and development and maintenance of a continuous learning culture (Figure 2). Moving from the current healthcare system to these LHS characteristics will require a re-engineering of



**Figure 2. The imperatives and characteristics of learning health-care systems.**

Modified from *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*.<sup>2</sup> Reprinted with permission from the National Academies Press. Copyright © 2013, National Academy of Sciences.

multiple areas: digital capture of the patient experience and real-time access to knowledge (ie, science and informatics); engaged and empowered patients, families, and communities participating actively in clinical decision making with their providers (ie, patient-physician partnerships); focus on the return on investment that care delivery provides (ie, incentives based on value and transparency); and health systems with leadership committed to a continuous learning culture and supportive system competencies.

The goal of this scientific statement is to provide an overview of how these LHS characteristics can be realized in one particular area of clinical medicine: CVD care. To this end, we explore how the LHS characteristics can be applied to CVD care to realize the informational and value imperatives outlined above. We also examine the current CVD care innovations in science and informatics, patient-physician partnerships, continuous learning cultures, and incentives. Finally, we provide recommendations for next steps and evaluation of the LHS development in CVD care. Our hope is that this statement will provide a current snapshot of the LHS development in CVD care and point to the next necessary steps needed for its realization in the myriad health systems—hospitals, medical groups, accountable care organizations—where CVD care occurs. We also hope this road map for realizing the LHS concepts in CVD care will inform similar efforts in the broader healthcare system.

## LHS SCIENCE AND INFORMATICS

In response to the informational imperative, the ideal LHS collects, organizes, and analyzes the massive amount of

clinical information available to providers and patients to provide tailored insights into optimal care decisions and delivery. These innovations in the availability and application of data, with tools such as predictive analytics, clinical decision support (CDS), and other knowledge management systems, can accelerate the diffusion of evidence to practice, identify gaps in care, and target interventions to the appropriate populations. The LHS also systematically collects information about the care delivered and its subsequent outcomes and uses it to inform innovation in optimal healthcare delivery and to generate hypotheses for new scientific discovery. For example, quantification of patients' unmet medical needs can suggest directions for subsequent research. In addition, candidates for research studies can be rapidly identified in such a system and, accompanied by automated enrollment and informed consent processes, fuel a point-of-care clinical research infrastructure that increases the speed and lowers the costs of conducting clinical research.<sup>5</sup>

Accordingly, the LHS requires a robust data infrastructure to provide real-time access to knowledge and digital capture of the care experience.<sup>2,6</sup> This infrastructure requires comprehensive data sources, thoughtful data oversight, and appropriate data uses. In this section, we describe the current state and examples of these data infrastructure domains in cardiovascular care, their current limitations, and suggested next steps for development.

## Data Sources

To achieve the LHS goals, data from the healthcare system are needed to determine whether the domains of

high-quality care are being met. These domains, as defined by the National Academy of Medicine in their 2001 report, *Crossing the Quality Chasm: A New Health System for the 21st Century*, include effectiveness, safety, timeliness, patient-centeredness, efficiency, and equity.<sup>7</sup> In addition, data from areas relevant to cardiac health outside the traditional structures of the healthcare delivery system such as patient-reported information and environmental data are also necessary to provide full “eyesight” into the various contributors to cardiovascular health and disease. To achieve these goals, data availability and timeliness are critical.<sup>8</sup> Without them, reliance on real-time, point-of-care assessments such as CDS, patient risk estimation, and some predictive analytic models is impossible. Even data applications that do not require immediate point-of-care data such as quality-of-care benchmarking and tracking of quality improvement interventions, longitudinal outcomes, and comparative-effectiveness studies still benefit from real-time data collection because timely data are essential to provide actionable insights to patients, clinicians, performance improvement personnel, healthcare administrative personnel, or other stakeholders.

Sources of data that capture the delivery of cardiovascular care are common and growing. Three important sources are electronic health records (EHRs), clinical registries, and administrative claims data. In addition to these, data sources that collect patient and environmental information beyond that collected in the context of the healthcare delivery system can provide unique and complementary information to cardiovascular care. Each data source has strengths and limitations but can, especially in combination, begin to provide a comprehensive view of the patient care experience necessary for the LHS.

## EHR Data

The EHR is a key data source for the LHS for a variety of reasons. First, EHR data are increasingly available as a result of the promulgation of both inpatient and outpatient EHR systems across the United States. Recent estimates indicate that nearly 95% of hospitals and almost 62% of cardiology practices have an EHR.<sup>9–11</sup> Second, EHR data have the potential to provide much more detail on patient-level encounters than administrative claims or other data sources.<sup>12</sup> Third, the immediate availability of data possible with EHRs allows its real-time use in clinical care, enabling point-of-care CDS, patient safety alerts, and patient risk estimation. The timeliness of this data also allows its frequent assessment to identify patient-reported outcomes, candidates for clinical trial enrollment, and practice trends for various patient populations (eg, practice, hospital, or community populations).<sup>13–17</sup> Fourth, EHR data can feed clinical registry programs to generate benchmarked quality and performance mea-

ures, with the caveat that this requires high-quality EHR data.<sup>18–20</sup> Finally, EHR data can be used in multicenter, national, or international clinical research studies.<sup>21–23</sup>

Several examples exist of cardiology programs that use EHR data to optimize clinical care. The Veterans Affairs (VA) healthcare system uses EHR data in its Clinical Assessment Reporting and Tracking (CART) cardiac quality program to support clinical care in VA cardiac catheterization laboratories.<sup>24,25</sup> CART uses a software application integrated within the VA’s EHR that uses structured data fields to collect patient and procedural information on all coronary procedures (ie, angiograms and percutaneous coronary interventions) performed in all VA cardiac catheterization laboratories nationally. It is designed to allow the treating provider to enter data at the point of care, allowing its immediate availability. Data are then used to support a variety of quality and safety initiatives. For example, one initiative actively detects procedural complications, in real time, across the VA system.<sup>26</sup> All major complications undergo a peer review by a national committee of interventional cardiologists, allowing rapid adjudication and an ability to broadly share quality improvement opportunities. Another initiative uses CART data to support point-of-care medical device surveillance, allowing immediate device malfunction detection.<sup>27</sup> Alerts are shared with the national VA cardiac community and with the US Food and Drug Administration. Finally, the CART program is piloting point-of-care CDS to determine risks for periprocedural acute kidney injury risk and bleeding.<sup>28</sup> These insights will inform procedural risk assessments and encourage the use of proven risk reduction strategies (eg, reduction in contrast dose, radial artery access).

In addition to these EHR-based initiatives to support clinical care, EHR-based data infrastructures have been established to facilitate clinical research.<sup>21,23,29,30</sup> Use of EHR data for this purpose provides a unique opportunity to address important questions that enhance the value of healthcare delivery for all of its key stakeholders.<sup>31,32</sup> Research infrastructures using EHR data include large, publicly funded initiatives such as the National Patient-Centered Clinical Research Network, public-private partnerships such as the High Value Healthcare Collaborative, and private initiatives such as Optum Labs.<sup>21,23,33</sup> An example of an EHR-based cardiovascular research initiative focused on generating new research insights is the Cardiovascular Research Network.<sup>21</sup> With support from the National Institutes of Health, this research consortium combines EHR data from 15 geographically diverse healthcare delivery systems that care for ≈11 million patients. A variety of data elements, including patient demographics, medical histories, treatments, and costs, were mapped from each system and combined into a virtual data warehouse that could be leveraged for large-scale research studies. Their initial studies generated important insights about real-world hypertension recognition,

treatment, and control; warfarin adherence and adverse clinical events in patients with atrial fibrillation (AF) and venous thromboembolism (VTE); and implantable cardioverter-defibrillator use in primary prevention.<sup>34–37</sup>

Although the availability of EHR data has significant potential for increasing the value of care in the LHS, a number of existing challenges need to be addressed to realize this value.<sup>38</sup> These include missing data (particularly data that directly inform clinical care), erroneous data, uninterpretable data, inconsistencies among providers and over time, and data stored in nonstructured text notes.<sup>39</sup> In addition, patients often receive care from multiple providers using different and poorly integrated EHR systems, thus making it difficult to completely track patients across practices or systems. Furthermore, critical clinical data are often recorded in unstructured, narrative text, complicating its use in LHS applications. Development of optimal EHR user interfaces is needed to minimize the deleterious effects of “alert fatigue” and other counterproductive effects of EHR-clinician interaction. In addition, effective user interfaces can improve the ease and consistency of data entry, which simultaneously reduces user burden and decreases the amount of unstructured, and potentially uninterpretable, data in the EHR. Finally, there is a major need for rigorous EHR evaluation and data optimization to ensure valid and usable information.<sup>40–42</sup>

In light of the potential and current limitations with EHR data, several next steps could significantly enhance its value. First, it would be ideal to create national data model and data storage standards to decrease the variability and to increase the utility of EHR data.<sup>39,42</sup> Second, EHR information exchange, which allows health systems to access and share EHR data across organizational and geographic boundaries, needs continued enhancement and dissemination to further increase the value of EHR data, particularly among patients who move among different healthcare systems.<sup>43</sup> National survey data from 2014 indicate that progress is being made, with 76% of hospitals reporting that they exchange health information with other hospitals, a 41% increase from 2008.<sup>44</sup> However, these efforts are fairly rudimentary in nature, relying on first-generation technologies such as direct messaging and query-based exchange, which are time-consuming and not integrated into clinical workflow. Third, EHR data by themselves may not be inclusive enough to conduct meaningful research. Rather, the value of EHR data may be realized when linked to other data sources such as administrative claims data, patient-reported behaviors, quantified-self data, and employer-based data. Finally, innovations in methods such as natural language processing are needed to reliably categorize the large amount of unstructured data that currently exist in EHRs.<sup>45–47</sup> As these and other innovations occur, EHR data will occupy a central role in generating meaningful knowledge in support of LHSs.

## Clinical Registry Data

Clinical registries, defined as observational databases of clinical conditions or therapies in which there are no registry-mandated approaches to therapy and relatively few inclusion or exclusion criteria, are another important source of data for the LHS.<sup>48</sup> They provide perhaps the most mature example of the “evidence informing practice” and “practice informing evidence” promises of the LHS. Clinical registries capture important information and events about specific conditions, procedures, or populations and use that information to evaluate and improve quality and outcomes.<sup>49</sup> In most cases, data are collected prospectively, following defined protocols that adhere to standardized definitions of clinical variables of interest. Aggregated data from the registries provide nearly real-time information that allows providers to compare their performance with national benchmark data, completing the cycle of improvement.

In cardiac care, established clinical registry programs such as the American Heart Association’s Get With The Guidelines (GWTG) programs, the Society of Thoracic Surgeons database programs, and the American College of Cardiology National Cardiovascular Data Registry have been essential in quality-of-care benchmarking, quality improvement interventions, longitudinal outcome assessments, and comparative-effectiveness studies.<sup>18,19,50,51</sup> For instance, GWTG-Stroke is a continuous quality improvement program focused on patients hospitalized with stroke and transient ischemic attack. With >3.6 million patient encounters across >1600 hospitals nationwide since 2001, the registry has been credited with contributing to sustained improvement in the use of evidence-based care.<sup>52</sup> Similarly, the GWTG-Heart Failure program focuses on systems of care to improve quality of care and outcomes for patients with heart failure (HF) and has captured data on >1.1 million patient encounters in >450 hospitals in the United States. Findings concerning the underuse of evidence-based therapies and the importance of early follow-up after discharge have been used to promote improved care in participating hospitals.<sup>53–55</sup>

Another example of using clinical registries to support care delivery is the American College of Cardiology’s Door-to-Balloon (D2B) initiative, which focused on the process measure of timely primary percutaneous coronary intervention for patients with ST-segment-elevation myocardial infarction.<sup>56</sup> Although clinical practice guidelines and performance measures had established a standard of providing primary percutaneous coronary intervention for patients with ST-segment-elevation myocardial infarction within 90 minutes of medical center presentation (also known as door-to-balloon time), clinical registry data demonstrated variable D2B times in the United States. In fact, in 2006, only 40% of hospitals had D2B times <90 minutes.<sup>57</sup> Using the registry data to iden-

tify these high-performing hospitals, investigators identified key processes of care associated with shorter D2B times such as direct activation of cardiac catheterization laboratory by the emergency department physician and having a cardiologist at the hospital at all times.<sup>58</sup> Armed with this knowledge, the American College of Cardiology then launched the D2B initiative, in which >1100 hospitals committed to implementing the key processes of care to lower D2B times. Using clinical registry data to track progress, implementation teams led adoption of the key processes and subsequently improved performance such that, by 2008, 75% of patients had D2B times within 90 minutes.<sup>59</sup> Furthermore, these improvements translated into significant and sustained improvements in patient outcomes, despite a large expansion of the population of patients with ST-segment–elevation myocardial infarction.<sup>60</sup> Initial success also led to the American Heart Association's Mission Lifeline initiative, promoting systems of care for patients with acute myocardial infarction to further coordinate the chain of survival for this acute cardiac condition.<sup>61</sup>

In addition to improving care, clinical registry data support the generation of clinical research and new scientific evidence. Research studies using registry data have provided comprehensive insights into the prevalence of cardiac conditions; demographic and clinical characteristics of patient populations; practice patterns; gaps in guideline-recommended care; time trends in disease presentation, management, and outcomes; and hypothesis-generating associations to inform prospective clinical trials.<sup>62</sup> These and other important insights have occurred in the hundreds of clinical research studies published from the specialty society GWTG, Society of Thoracic Surgeons, and National Cardiovascular Data Registry programs, in addition to many more from health system clinical registry programs of the VA, Cardiovascular Research Network, and others.<sup>34,36,63–88</sup>

As with EHRs, clinical registries have limitations. There is often a time lag between care delivery and collection of data in a clinical registry, which can prevent timely insights into and actions to improving care. In addition, data are often manually collected by human abstractors, which contributes to this time lag, can result in transcription errors, and adds significant expense to the collection process. Many registries are focused on single conditions or treatments, limiting their ability to assess the full care experience. Finally, many registries have variable participation of their targeted patients and health systems, which can undermine the representativeness of the registry.

Given these limitations, the next steps to improve the utility of registries include using structured data capture from the EHR to supplement, or in some cases, replace the need for manual abstraction.<sup>89</sup> In addition, clinical registries should be linked to claims and other data sources to expand the data infrastructure from which to

conduct analyses to inform healthcare delivery. Continuing efforts to combine registries with these other data sources appear to be the most fruitful way to maximize their value in the LHS.

### Administrative Claims Data

Administrative claims data, generated from healthcare invoices to payers, are the most widely available data in the US healthcare system. Similar to clinical registry data, claims can be useful for assessing disease incidence, management, and outcomes. In addition, claims, because they are tied to a payer rather than to a single EHR or clinical registry, are particularly valuable in evaluating resource use across settings and tracking episodes of care across time (eg, rehospitalization after a procedure), thus providing important insights for hospitals, health systems, and payers. These insights can, in turn, drive programs focused on improving care delivery and outcomes.

A prominent example of using claims data to support more efficient care is the Hospital Readmissions Reduction Program from the Centers for Medicare & Medicaid Services. Analysis of Centers for Medicare & Medicaid Services claims data demonstrated frequent rehospitalizations in the 30 days after admission for HF and acute myocardial infarction,<sup>90</sup> and rehospitalization rates were highly variable across US hospitals. As a result, these insights fueled both public reporting of 30-day rehospitalization measures and health policy changes that levied payment penalties on hospitals with excessively high rehospitalization rates.<sup>91</sup> These changes, in turn, led to significant decreases in rehospitalization rates.<sup>92</sup>

Like all data sources, claims data have limitations. First, data are dependent on accurate coding of clinical conditions and events, which does not consistently occur. For example, different providers may have different methods of coding encounters, which can limit interprovider comparability. In addition, consistent biases in coding such as “up-coding” can significantly impair the veracity of claims data insights. Nonetheless, *International Classification of Diseases* codes have demonstrated accuracy in characterizing CVD conditions and care.<sup>93–95</sup> Second, aspects of care that are important clinically (such as patient preferences) but not relevant from a financial reimbursement point of view are typically not collected in these data. Third, the availability of claims data is dependent on a reimbursable care episode occurring. As a result, clinical events and safety signals that occur outside the delivery system are not detected. Furthermore, as the United States moves increasingly toward alternative payment models in which claims are not generated for each service rendered such as bundled payments and some accountable care organization programs, claims data may become less informative to actual care delivery. Fourth, many patients switch payers

during the course of their life, and few payers combine their claims data. Thus, patients with multiple payers over time cannot be consistently followed up, although this is less of an issue for individuals >65 years of age or otherwise qualifying for Medicare. Finally, claims data often lack critical clinical details such as indications for procedures, disease severity measures, and other clinical information necessary for accurate risk adjustment and correct characterization of clinical outcomes.

As with EHRs and clinical registries, an important next step to improve the utility of claims data is to combine them with other data sources such as registries and EHRs, which may fill the gaps that claims data have in terms of rich clinical detail. In addition, many states have established all-payer claims databases that allow a more comprehensive assessment of both patients and populations, and these efforts should be supported and expanded. Finally, as reimbursement policies change to compensate quality of care, rather than merely the occurrence of care, claims data should evolve in response to provide a more comprehensive view of healthcare delivery.

### Supplemental Data Sources

Although EHR, registry, and claims data are all essential sources of care delivery information, they alone cannot provide a comprehensive view of the various contributors to a patient's cardiac health, particularly those influences that occur outside the setting of the healthcare delivery system. Accordingly, the LHS will need to develop, integrate, and ultimately act on supplemental sources of data that can provide important insights into untapped aspects of patient health.

Broadly speaking, supplemental data sources can be categorized into patient-reported data and environmental data. Patient-reported data include information such as health status (ie, symptoms, functional status, and quality of life)<sup>96</sup> and physiological measures (eg, blood pressure, volume status), which can be collected through traditional methods of inquiry (eg, questionnaires) or newer forms of data collection such as implantable medical devices (eg, CardioMEMs) and wearables (e.g. FitBit). Collecting and integrating information from these and other domains can provide a more comprehensive assessment of a patient's cardiac health and potentially enhance the ability of the LHS to proactively anticipate and react to declines or improvements in cardiac health. However, supplemental data sources are nascent, and substantial work is needed to develop methods for collection, analysis, and use. Further details on patient-reported data are presented in LHS Patient-Clinician Partnerships.

Similar to patient-reported data, environmental data can complement more traditional data sources in characterizing influences on patients' cardiac health. An example of environmental data is information about the

"built" environment where patients live, defined as the man-made surroundings that provide the setting for human activity, including buildings, green space, water supply, food access, and other environmental elements.<sup>97</sup> Although these data sources, like patient-reported sources, are nascent in healthcare applications, early examples of their collection and use in cardiac care exist. For instance, the built environment can affect cardiac health via ambient air pollution. This association was demonstrated by investigators who used data from the US Environmental Protection Agency air quality monitoring network to assess the relationship between coarse particulate matter levels and cardiovascular hospitalizations among 110 large urban US counties.<sup>98</sup> Researchers found that increased air pollution levels were associated with higher rates of hospitalizations in elderly patients, suggesting that actions such as counseling patients to remain indoors during high-pollution days may have an impact on overall cardiac health.

Other environmental data sources include economic and political data that characterize societal influences on cardiac health and social network data that describe family, community, and other social influences on patients. For example, economic data on median income levels of neighborhoods were correlated to various cardiac outcomes such as receipt of coronary intervention after acute coronary syndrome,<sup>99,100</sup> mortality after myocardial infarction,<sup>99-101</sup> mortality after stroke,<sup>102,103</sup> and receipt of bystander cardiopulmonary resuscitation.<sup>104</sup> Similarly, in social network data analyses, obesity was associated with the prevalence of obesity in family and friends.<sup>105</sup> These initial observations suggest that economic and social influences outside the care delivery system drive cardiac health outcomes and may need direct action to maximize cardiac health, insights that would not occur without the collection and integration of alternative data sources into the overall data infrastructure of the LHS.

Despite their promise, effective use of alternate data sources will require overcoming a variety of barriers. First, the systematic collection of this data is fragmented and incomplete. Certain data sources such as Census data are more likely to be incomplete in areas of lower socioeconomic status, preventing insights and potential assistance for populations at higher risk for cardiac disease.<sup>106</sup> Second, integrating alternative data sources with more traditional healthcare delivery data such as EHR data will require proper patient matching and correlation with location and behaviors. Finally, generating actionable insights from the combination of varied data sources will require designing and testing interventions suggested by observed associations such as those described above.

The potential that alternative data sources offer for broadening the reach of data infrastructure in the LHS to inform and optimize patients' cardiac health is signifi-

cant and worthy of the necessary investment. The next steps to develop these data sources should include partnerships with organizations that have data likely to be informative to patient health (eg, social service organizations, environmental monitoring agencies). In addition, support should be given to merge these data with more traditional healthcare delivery data, to conduct analyses to better understand the insights that these combined data sets can provide about cardiac health and disease, and to design innovative interventions (eg, extending cardiac risk factor screening programs to social communities, providing proactive guidance about avoiding environmental triggers in cardiac patients) to capitalize on these insights.

### Data Oversight

Data oversight, which encompasses data governance, regulation, privacy protection, and data security, has an essential supporting function for the LHS data infrastructure, and it requires attention to maximize the LHS potential. Because the data infrastructure contains sensitive health information about individual patients and patient populations, “rules of the road” are needed to ensure that data will be used for the common good, that transparency of governance functions and activities exists, and that there is an overarching intent to protect privacy and assure the security of data.

Although best practices for data oversight are not standardized, general considerations include specifying the overall goals and intent of data use, governance structures and processes, and privacy protections.<sup>6</sup> One example of specifying goals of data use is articulating a mission statement such as “To foster data utility for the common good, cultivating a bond of trust with the public and between data-sharing entities to accelerate collaborative progress towards the creation of a learning healthcare system.”<sup>6</sup> Establishing a unifying goal can provide guidance for governance and use and allow a standard that can be regularly revisited to ensure fidelity of the overarching mission of LHS. For example, such a goal could guide access to the cardiovascular registries outlined above (National Cardiovascular Data Registry, GWTG, etc). Currently, organizations contributing to these registries do not always have ready access to its insights. Data use standards could ensure that healthcare systems have sufficient access to registry data to support quality improvement and other LHS activities.

Governance structures for the LHS can take many forms, and there is no clear advantage of one over the other. For example, data use decisions and oversight may be centralized under one governing body housed in the leadership of the health system or decentralized among a variety of entities that collectively contribute data and leadership to the LHS. Similarly, the source of governance authority may derive from a health system,

a governmental mandate, or the patient population under the care of the system. Regardless of the structure or source of authority, it is important that governance be clearly articulated and transparent to ensure accountability. Furthermore, effective governance will need to maintain the trust of all participating entities. For example, protections should be established to ensure that one healthcare system does not use LHS data to achieve an unfair business advantage over another. In addition, governance will be needed to adjudicate questions of data ownership. Although health systems may wish to commoditize their insights, it will be important to ensure that this business interest does not supersede the LHS goals.

As with all sensitive data, privacy protection is critical. However, because LHS data simultaneously serve in clinical, operational, and research functions, the traditional forms of privacy protection, deidentification of data and restriction of access, are not practicable or even feasible. Accordingly, LHS data privacy needs to balance 3 technical and human considerations: techniques for deidentification, trustworthiness of the recipient, and physical security on which the data will reside. For example, text notes on patients being analyzed for quality improvement opportunities may be able to be only partially stripped of identifying information. As a result, to facilitate data acquisition and analysis, only those members of the LHS who are entrusted with this kind of data will be authorized to access the data, and they must have a reasonably secure location for data storage and analysis. Providing a balance between technical and human factors in ensuring privacy is a departure from the traditional research infrastructure (which generally requires anonymization of patient data) but is necessary to allow the effective use of data in service of LHS goals.

Similarly, regulatory frameworks that have traditionally governed clinical research will need adaptation to the LHS structure.<sup>107</sup> In the past, research and clinical practices have been kept largely separate, primarily to avoid “therapeutic misconception,” in which patients enrolled in clinical research may “...[fail] to appreciate the difference between research and treatment.”<sup>108–110</sup> As a result, clinical research requires extensive regulation, including institutional review board oversight, informed consent, and HIPAA (Health Insurance Portability and Accountability Act) requirements. In contrast, quality improvement activities aimed at improving processes or patient management are generally exempted from these activities, primarily because they generally address factors occurring at a local level and thus do not meet a key criterion of clinical research: producing generalizable knowledge.<sup>111</sup> Because the LHS uses its data infrastructure to serve both clinical research and practice, synchronization of regulations and procedures will need to occur in a way that balances the need for patient autonomy and awareness in the conduct of clinical research

with the need to analyze data and generate actionable insights in a timely manner. For example, one proposed framework suggests that quality improvement activities should be classified as routine and nonroutine practices, with the nonroutine practices undergoing more comprehensive review by an institutional review board specially trained in such research methodology and the potential risks that it introduces to patients.<sup>112</sup>

## Data Uses

The comprehensive collection of health data is only the first step in constructing the LHS. Analyzing and using the data to tailor care for both individuals and populations, to study and improve methods of healthcare delivery, and to conduct clinical research is necessary to realize the full potential of the LHS. Promising methods are emerging to support all 3 of these objectives. Predictive analytics and CDS can assist in tailoring care to individuals and populations. The developing field of quality improvement and implementation science can inform innovations in healthcare delivery. Finally, EHR tools are being developed to enable rapid screening of patients for clinical trial eligibility and to assist in more efficient clinical trial conduction.

## Predictive Analytics

Predictive analytics is a broad term but generally means the discovery and analysis of patterns in data to predict populations, responses to treatments, or outcomes for various disease states.<sup>13</sup> As the LHS data infrastructure continues to grow and mature, predictive analytic tools will be fundamental in transforming these data into actionable insights.<sup>113</sup> In addition, as mentioned above, as new patient and environmental data sources become available, predictive analytic techniques will be integral in understanding how the aggregated information can best be harnessed to determine the best approach to maximizing both individual and population health.<sup>114</sup> Finally, with the integration of predictive analytic tools into EHRs, insights can be generated at the point of clinical care, allowing minute-by-minute assessments and changes in clinical management to optimize care. All of these predictive analytics applications serve to further support the LHS science and informatics characteristic that digitally captures and integrates patient information to provide real-time access to clinical knowledge and continual learning.

Innovations in predictive analytics in cardiovascular care, often in conjunction with commercial technology companies, are underway in both hospitalized and ambulatory patient settings. For example, in the hospital setting, commercial systems have been developed that use computerized continuous monitoring of heart and respiratory rates in medical and surgical patients to predict

unexpected clinical deterioration.<sup>115</sup> The system has a piezoelectric motion detector, placed under the patient's mattress, that continuously monitors the patient's heart rate, respiration, and movement. This form of continuous, real-time data monitoring for intensive care unit patients resulted in shorter hospital lengths of stay, lower code-blue rates, and shorter intensive care unit lengths of stay compared with patients who received traditional monitoring.

In the ambulatory arena, predictive analytics have shown early promise in patients with advanced HF.<sup>15</sup> Using an EHR-based software platform, investigators used a predictive analytic model that identified patients with HF at high risk for readmission. Patients identified as high risk received an intensive set of evidence-based interventions to reduce readmission such as case coordination and early follow-up appointments with both HF specialists and primary care providers. At the completion of the study, 30-day readmissions decreased by 25% compared with a control group.<sup>15</sup> Another example of using both predictive analytics and a novel source of patient information in ambulatory cardiovascular care is the aforementioned CardioMEMs HF system (St. Jude Medical, St. Paul, MN).<sup>116</sup> The system consists of a pressure sensor that is permanently implanted via cardiac catheterization into the pulmonary artery. The device communicates with an external data collection and processing unit that transmits pulmonary artery pressure, pressure waveforms, and heart rate data to a cloud-based secure website, allowing early detection of worsening HF. In initial clinical trials of this device among patients with New York Heart Association class III HF, patients with the device had a 37% reduction ( $P < 0.0001$ ) in HF hospitalizations over a mean follow-up of 15 months.<sup>116</sup>

Although these early examples are promising, a variety of innovations in predictive analytics are needed. First, effective prediction is wholly reliant on the underlying quality of its data. Thus, there is a need for consistent care documentation, common data elements, data interoperability, and capture of semistructured and structured data to fully harness data necessary for effective predictive analytics.<sup>45,89,116–118</sup> Second, emerging data sources such as genomic information will require organization in a manner that can be effectively applied to analytics engines. Third, there is significant complexity in techniques that assess large amounts of data and generate insights. Thus, rigorous methods of evaluating and validating predictive analytic performance are needed. In addition, clinicians will need to become comfortable with a certain degree of "black box" methodology in predictive analytics. Fourth, the techniques and methodologies of predictive algorithms, assessment scores, visual representations, and other aspects of the analytics themselves need to be further developed so that systems provide the best representation of the information to the appropriate individual in the right context and at

the right time. Fifth, privacy and ethics issues unique to predictive analytics will also need attention. For example, if predictive analytic algorithms recommended intervention on only a subset of patients, there may be an ethical and legal basis to inform patients not selected for the intervention of such a decision.<sup>16</sup> Similarly, the optimal regulation of insights generated from predictive analytic algorithms will need definition, particular if they lead to clinical action or inaction. Although the US Food and Drug Administration has recently issued guidance on the regulation of mobile medical devices, no such regulatory structure currently exists for these insights, despite their clear role in dictating health care for selected patients.<sup>119</sup> Finally, in cases when predictive analytic tools are being developed in conjunction with commercial companies, it is important to ensure that effective regulation is in place that strikes a balance between protecting patient needs and encouraging innovation.

Although the field of predictive analytics is nascent, opportunities for its use already exist. In a recent issue of *Health Affairs*, Bates and colleagues<sup>13</sup> outlined potential “use” cases for predictive analytics on the basis of their ability to be performed on currently available EHR data and potential for significant healthcare cost savings (Table 1). Adapting these cases to cardiovascular conditions may represent a possible pathway for driving the development of the infrastructure, technologies, and resources necessary to accomplish and leverage predictive analytics in cardiovascular medicine.

### Clinical Decision Support

The fundamental purpose of collecting data and using tools such as predictive analytics to generate insights is to inform clinical action. However, the sheer amount of information needed to tailor treatment decisions to individual patients is often overwhelming. As a result, there has been considerable development of CDS programs specific to CVD in recent years. Most of this progress can be grouped into 3 categories: providing predictive risk model information at the point of care; providing point-of-order feedback and guidance on the appropriateness of diagnostic testing, treatments, and other clinical care decisions; and tailoring clinical information to specific patient needs at the point of care. Thoughtful development and use of CDS programs can respond to the informational imperative of the LHS by organizing information to provide the right care to the right patient at the right time.

Use of empirically derived predictive models to guide therapy in cardiovascular care is increasingly common. Notable examples include the CHA<sub>2</sub>DS<sub>2</sub>-VASc<sup>120</sup> score for assessing the risk of thromboembolism in patients with nonvalvular AF, the atherosclerotic cardiovascular disease pooled cohort equations<sup>121,122</sup> for estimating the 10-year and lifetime risks of sustaining a complication

**Table 1. Potential Applications for Predictive Analytics in LHSs**

High-cost patients	Identify patients early for intensive treatment
	Provide longitudinal case management for those most likely to benefit
Anticipating readmissions	Identify patients at risk for readmission early for resource deployment and tailored interventions
	Provide longitudinal follow-up and monitoring
Patient triage	Identify patients at risk for acute adverse outcomes
	Assign them to the appropriate level of care
Preventing clinical decompensation	Identify inpatients at risk for decompensation
	Improve the signal-to-noise ratio for clinical alerts to reduce alarm fatigue
	Intervene to prevent adverse events
Predicting adverse clinical events	Identify patients at risk for adverse events such as acute kidney injury, infection, or adverse drug events
Projecting the trajectory of disease	Identify the time course of disease progression
	Improve the timing of therapeutics in line with progression
	Optimize treatment, particularly in those diseases that affect multiple organ systems and result in significant morbidity

LHS indicates learning healthcare system.

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of atherosclerotic cardiovascular disease (death, myocardial infarction, stroke), the SYNTAX score<sup>123,124</sup> for quantitatively representing the complexity of multivessel coronary artery disease and predicting outcomes by revascularization strategy, and the Society of Thoracic Surgeons' surgical risk calculator<sup>125–128</sup> for estimating morbidity and mortality after a variety of cardiothoracic surgical procedures. However, despite their utility in clinical decision making, these scoring systems have not been tightly integrated into EHR systems. Instead, data must be manually entered into a dedicated app or Web-based tool. Then, clinicians must manually transcribe data into the EHR if the data are to be retained as documentation. Lack of integration with clinical workflows, coupled with the wide variety of data needed for accurate calculations, limits broader use except in relatively specialized clinics.<sup>129–131</sup>

To address these limitations, the next phase in the evolution of cardiovascular CDS is real-time, patient-specific risk prediction based on clinical data automatically extracted from EHR and other health information technology systems. Unfortunately, tight integration between real-time analytics and intervention to provide CDS is more the exception than the rule. A 2011 review of 26 peer-reviewed risk prediction models for hospital readmission identified only 3 models that were integrated into an EHR and designed to identify high-risk patients in real time.<sup>16,132</sup> One example is the implementation of the previously described Parkland Heart Failure Readmission Risk Score into the EpicSystems EHR (Epic Systems Corp, Verona, WI).<sup>133</sup> This empirically derived model estimates the likelihood of 30-day readmission after hospitalization for HF. It has been used to manage resource allocation, including intensive patient education, multidisciplinary discharge planning, and accelerated outpatient follow-up. Importantly, this application of CDS was associated with a 27% adjusted relative reduction in the rate of 30-day readmission.<sup>15</sup>

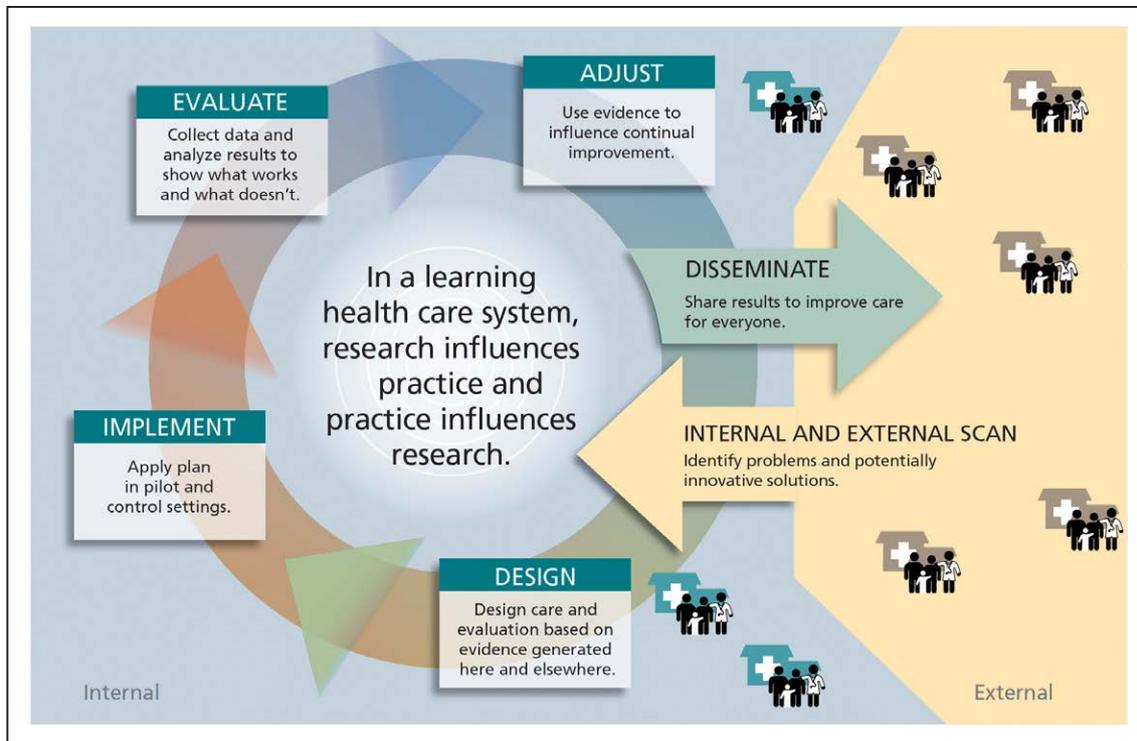
Another developing area for CDS is its use in guiding appropriate care; that is, care that meets guideline-based standards codified into appropriate use criteria. There have been early efforts in developing these programs in radiology, and there is increasing evidence that similar point-of-care systems may also increase appropriate and decrease inappropriate evaluations for ischemic heart disease<sup>134</sup> and improve the diagnostic yield of echocardiography.<sup>135</sup> The utility of appropriate use criteria in diagnostic coronary angiography is less clear,<sup>136</sup> although it may have some benefit in coronary revascularization.<sup>137</sup> Several smartphone applications have been developed that provide the clinician the opportunity to access cardiovascular appropriate use criteria at the bedside. For example, the American College of Cardiology launched the FOCUS program, which tracks appropriate use of cardiac imaging procedures and attempts to improve them using a point-of-care CDS system, a performance improvement process, and a learning community.<sup>138</sup> Another example from the VA is the CART program, which uses both patient-reported anginal burden with natural language processing–derived stress testing information to guide appropriate use of elective percutaneous coronary intervention procedures.<sup>24</sup> However, in the absence of a regulatory mandate, widespread implementation and integration of cardiology appropriate use assessment into EHR documentation workflows have yet to be accomplished.

Although the role of CDS in prediction and appropriateness is important, the potential for CDS is arguably greatest in its ability to guide real-time management decisions for patients by supplementing clinicians' decision making with the vast and growing data from medical research, clinical guidelines, and empirical outcomes from patients similar to the patient under treatment.<sup>139</sup> However, such

CDS systems are still quite early in their development lifecycle. Current examples include VTE prevention, dyslipidemia screening and treatment, and anticoagulation in AF.<sup>140</sup> One program, based at Brigham and Women's Hospital in Boston, used EHR data to identify patients at high risk for VTE by their clinical risk factors and then prompted clinicians to order VTE prophylaxis medications.<sup>141</sup> As a result of the program, orders for medications increased by nearly 20%, the risk of symptomatic VTE decreased by 41%, and no significant differences in bleeding were observed. Another program focused on optimizing anticoagulation in AF patients in Europe using a computer-assisted CDS program.<sup>142</sup> After implementation of the program, the time spent in therapeutic range for patients on warfarin significantly improved.

Although these initial examples are encouraging, effective CDS use in cardiovascular care will take continued innovation, particularly in its implementation and incentives. Traditionally, successful CDS implementation has relied largely on comparisons of clinician behavior. For example, the effects of an appropriate use criteria–related CDS application might be ascertained by improvements in rates of both appropriate and inappropriate test orders before and after implementation.<sup>143</sup> Although this metric is useful, additional components must also be considered in the evaluation of the effectiveness of a CDS application.<sup>144</sup> Specifically, an application must be evaluated to assess whether it activates on the right patients at the right time at the intended point in clinical workflows, whether it makes the correct recommendations based on available information, how and why it affects provider decision-making behavior,<sup>145</sup> and its effects on patient outcomes; for example, whether the patient underwent the appropriate test, received the correct medication, or avoided an adverse event.<sup>146</sup> In addition, evaluation should track and analyze instances in which reliance on CDS resulted in an adverse clinical event so that CDS algorithms and use can be optimized to ensure patient safety. Such evaluations require robust reporting resources and analytics expertise. Furthermore, the development of truly integrated cardiovascular CDS applications using real-time patient data to generate feedback to providers at the time of clinical decision making within normal workflows remains the objective. Technical advances such as Health Level 7 Fast Healthcare Interoperability Resources and the greater availability of Web services should promote innovation in this area in coming years.<sup>147,148</sup>

Similarly, incentives for CDS use need attention. Currently, the largest known effort is the Centers for Medicare & Medicaid Services EHR Meaningful Use Incentive Program, which includes a foundational requirement that certified EHR technologies include CDS functionality.<sup>149</sup> In the program, CDS is defined and qualified on the basis of its relationship to a reportable clinical quality measure, as specified by the program. For example, a Centers for Medi-



**Figure 3. The 6 phases of the rapid-learning healthcare system, from scanning to dissemination.**

From Greene et al.<sup>1</sup> All rights reserved. Reprinted with the permission of the American College of Physicians. Copyright © 2012, American College of Physicians.

care & Medicaid Services—qualifying CDS algorithm would be one that prompts clinicians to consider aspirin therapy in patients with coronary artery disease because a clinical quality measure exists that reports the proportion of patients with coronary artery disease who are prescribed aspirin. Although this approach is restrictive in terms of what qualifies as CDS, the linkage with clinical quality measure reporting provides a focus for the development of the technical components still needed to automate useful CDS.

### Quality Improvement and Healthcare Delivery Evaluation

The LHS design, by its nature, allows efficient implementation and evaluation of quality improvement. Quality improvement efforts seek to assess the current state of healthcare delivery and then make adjustments to those processes to improve their delivery and associated outcomes. The LHS data infrastructure provides an ideal platform to support these efforts because they require collection and analysis of clinical data to assess both clinical care and the impact of interventions.

One illustration of the LHS role in quality improvement is the framework used by the Group Health Cooperative, a nonprofit, integrated healthcare system providing care and coverage to ≈650 000 people in Washington State.<sup>1</sup> In the course of designing a patient-centered medical home, researchers devised a methodological approach

that simultaneously informed quality improvement and care redesign projects and provided insights into how the LHS, with its data infrastructure and research methods embedded in real-world clinical settings, can provide the technical tools and the culture to achieve transformational learning that benefits both clinical practice and broader generalized knowledge (Figure 3).

Group Health's approach consists of 6 elements, modeled loosely on the well-articulated plan-do-study-act cycle: internal and external scans, intervention design, implementation, evaluation, iterative adjustment, and dissemination.<sup>150</sup> Internal scans identify gaps in care that have significant impacts on patient outcomes and are accompanied by external scans of the clinical and health services research literature to identify potential solutions. An intervention is then designed in conjunction with local stakeholders to ensure that it accounts for contextual factors that affect care. Importantly, interventions use a pragmatic research design that balances the need for rigorous evaluation with the rapid deployment needed for operational needs. Accordingly, implementation of the intervention is generally accomplished with the use of stepped approaches and concurrent controls so that unanticipated contextual factors can be identified and incorporated, buy-in can be achieved from stakeholders, and intervention effects can be separated from secular trends in care and outcomes. Evaluation with feedback, using real-time data, allows the assess-

ment of intended and unintended consequences of the intervention, identifies those core components of the intervention that are necessary for translation to other settings, and provides “good enough” data to match the pace of contemporary health care without waiting for the staid pace of traditional research projects. Effective evaluation also deploys methods such as randomization and independent data collection that can accurately distinguish the impact of the intervention on improved performance from improved documentation or other Hawthorne effect influences. Iterative adjustment allows continual modification of the intervention to account for changing external factors and new information while preserving the core benefit of the intervention and allowing its sustainability over time. Finally, dissemination of new knowledge to other healthcare settings is essential. The traditional forms of knowledge generation and sharing, primarily peer-reviewed literature, are often too slow to effectively inform ongoing healthcare delivery innovation. Therefore, it must be accompanied by other forms of more rapid communication.

Several national examples of quality improvement initiatives for cardiac conditions provide insights into how the LHS approaches illustrated by Group Health can have meaningful impact. The American Heart Association’s GWTG–Coronary Artery Disease program was developed to address quality gaps in the secondary prevention management of hospitalized patients with CVD.<sup>151</sup> In line with the quality improvement execution concepts outlined above, quality gaps in the secondary prevention management of cardiac patients were identified, and the best evidence for their optimal treatment was derived from the professional society guidelines. An intervention using a Web-based patient management tool that provided data entry, CDS, and provider feedback was developed and pilot tested in 24 hospitals. After an evaluation of the initial effort and iterative adjustment based on participant feedback, the program was implemented nationally. In an evaluation of the program, overall guideline adherence among program participants improved significantly, albeit by a relatively modest 5%, and improvements persisted over time.<sup>152,153</sup> The GWTG–Coronary Artery Disease leadership team published these findings in the peer-reviewed literature, but it also conducted a broad marketing and recognition campaign for participating hospitals, allowing dissemination of the impact of the program in multiple channels.<sup>154</sup> Building on this initial success, the American Heart Association organized a variety of quality improvement programs under the GWTG umbrella and made significant improvements in the quality of care for patients hospitalized for HF, stroke, and cardiac arrest.<sup>155–157</sup>

### LHSs and Clinical Trials

In addition to supporting optimal clinical practice, the LHS can support clinical research and evidence gen-

eration. In particular, effective use of the real-time data generated in LHS environments can identify potential candidates for clinical study enrollment and increase efficiency in study execution.

Historically, the process for identifying eligible patients for clinical trials has been highly inefficient and costly. In most cases, trial enrollment was dependent on direct patient referrals from clinicians who were both aware of the study and motivated enough to make referrals. Perhaps unsurprisingly, this rarely occurred. For example, in a recent evaluation of a national US acute coronary syndrome registry, researchers found that only ≈3% of patients eligible for clinical trials were actually enrolled.<sup>64</sup> Low enrollment rates increase trial costs by prolonging the enrollment period and increasing the number of sites needed to complete the trial. For example, in a Tufts University study, investigators found that between 2000 and 2011 the average number of procedures per trial protocol rose 60% and the number of case report form pages per study nearly tripled.<sup>158</sup> These inefficiencies are estimated to add between \$4 to \$6 billion to drug development costs. Furthermore, low and inefficient enrollment in the United States contributed to increased movement of clinical trial conduct to developing countries, adding challenges to the quality of trial data, ethics concerns, and questions about trial generalizability.<sup>159</sup>

These inefficiencies in trial enrollment can be improved with the use of the real-time data from EHRs and other data sources inherent in the LHS. For example, EHRs could allow site investigators to carry out detailed patient queries to prospectively identify and enroll those who meet trial inclusion and exclusion criteria. Similarly, algorithms built on trial inclusion criteria could be integrated into EHRs and alert clinicians to the patient’s eligibility for clinical trials during the course of routine clinical care. Once identified, these patients can be approached for trial enrollment or even prospectively contacted to determine their initial interest in the trial. Those interested can then be brought in for specific screening clinic visits for efficient mass enrollment.

The LHS can also improve current inefficiencies in trial data collection and management. For example, sites can use data from patients’ EHRs to automatically import routinely collected clinical data items into a trial case report form. Additionally, the EHR can facilitate protocol fidelity, helping sites with study order sets, follow-up reminders, and other prompts for safety concerns. The EHR can also support more efficient patient trial follow-up and end-point determination. Specifically, once a patient has consented to a given trial, clinical visits, medication adherence, clinical outcomes, and other information relevant to the trial can be accessed via the EHR. Finally, the LHS is well suited to support pragmatic clinical trials. Pragmatic trials are designed to evaluate the effectiveness of interventions in real-life routine practice

conditions.<sup>160</sup> Therefore, the EHR can provide important information about enrollees' routine care and aggregate the data to measure the impact of the trial intervention on the targeted outcomes relative to the control group.

Examples of EHR-enabled trials in CVD are already available. Investigators in Sweden used one of their electronic data registries to successfully conduct a nationwide, randomized, clinical trial, TASTE (Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia).<sup>161,162</sup> The TASTE trial used real-time, electronic patient screening and point-of-care clinician prompts to facilitate enrollment of nearly 60% of the patients eligible for the study, with a substantial reduction in trial conduction costs. Similarly, investigators in the US Department of Veterans Affairs are demonstrating the promise of electronic patient screening and investigator prompting to speed enrollment in a physical activity trial for overweight veterans.<sup>163</sup> The Patient-Centered Outcomes Research Institute recently announced that it was designing a trial that will screen EHRs of several health systems (each with >1 million patients) to identify those eligible for an aspirin dosing trial.<sup>164</sup> Those individuals found to be eligible will then be solicited by e-mail for potential trial enrollment. Finally, investigators at Geisinger Health System tested a multifaceted intervention to improve physician performance in diabetes mellitus care.<sup>165</sup> Using EHR-facilitated audit and feedback, computerized reminders, and financial incentives, investigators demonstrated significant improvements in glucose control, blood pressure control, and vaccination use among diabetic patients.

Despite many promising examples, challenges and barriers to routine use of EHRs to assist with trial enrollment and conduction need attention. For example, although most US hospitals have adopted EHRs,<sup>10</sup> there is significant variability in the data elements collected, their definitions, and the underlying data quality. Accordingly, broad adoption of data standards, improved data quality, and other operational agreements for data sharing and interoperability are needed. Another area of focus is research regulatory oversight. Patient privacy concerns, central institutional review board approval, and patient safety monitoring parameters will need clarification and refinement to allow EHR data to be used effectively.<sup>166</sup>

### LHS PATIENT-CLINICIAN PARTNERSHIPS

A fundamental component of the LHS is engaged, empowered patients and strong partnerships with their clinicians. Patients have a large role to play in the LHS by providing important information on their health and the various behaviors, environments, and interactions that affect it. Provision of this information requires the same data collection and distillation techniques described above but with the added task of translating the insights into a form understandable by and tailored for patients

to guide their actions in achieving and maintaining their health. In particular, preference-sensitive medical decisions require consideration and integration of patients' preferences and values, information that only patients can provide.<sup>167,168</sup> Ideally, this information will provide useful guidance for patients' health care and, ultimately, health. As the value of this information is realized, it can potentially incent healthcare systems to carefully listen to their patients and patients to deeply engage with their own health care to maximize their health. In this section, we describe the current state of patient-generated information and patient use of the LHS data, their current limitations, and suggested next steps for development.

### Patient-Reported Information

Patient-reported information can enhance data generated from the healthcare delivery system, allowing a more comprehensive view of patients' health. Ideally, the information can provide further insights into factors associated with health and offer opportunities for its improvement. This information from and relevant to patients can be gathered in a variety of ways. First, patient-reported outcomes, which are reports of a patient's health status that are directly collected from patients through surveys or other tools, are increasingly recognized as a fundamental component of healthcare delivery. A variety of efforts have been made in determining the best methods for patient-reported outcome collection and integration into care.<sup>169-171</sup> Second, biometric sensors that are integrated into wearable devices that many patients often use such as wearable devices or health applications on a smartphone are another promising area for focus. For example, implantable cardiac devices can be leveraged to provide extensive and frequent physiological monitoring. Third, the development of mobile and Web-based applications for patient engagement and self-management also continues to increase. Although there continues to be a need for better evidence of the impact of these applications, a number of innovations have been tested for cardiovascular care. For example, Web-based delivery of a virtual cardiac rehabilitation program was safe and effective for CVD risk reduction.<sup>172</sup> Similarly, mobile messaging was associated with greater physical activity and weight loss.<sup>173</sup> These early successes have prompted the ongoing development of other mobile applications to improve health-related behaviors such as smoking cessation and medication adherence. Fourth, online patient portals through which patients can track their own data, access their medical information, and communicate with their healthcare providers are another potential source for important information. Patient portals are in their infancy, but their use is on the rise. Typical uses include tracking laboratory and biometric data, sending messages to providers, preparing for visits, requesting prescription refills, and reviewing a visit summary.<sup>174</sup> The impact

of patient portals on health is largely unknown, but in one report, use was associated with greater adherence to statins and lower low-density lipoprotein levels.<sup>175</sup> Together, these new technologies and new approaches reveal a shift in our appreciation for the value of patient-collected data obtained outside the conventional clinic setting. In addition, there is growing recognition among funders that research into this area is needed. For example, the Patient-Centered Outcomes Research Institute is taking important strides toward conducting major clinical research studies that are both patient-centered and patient-powered and often involve collecting and using patient-reported information.<sup>176</sup>

A variety of early initiatives that gather and use patient-reported information in CVD have shown initial promise in AF, medication adherence, hypertension, HF, and remote monitoring of implantable cardioverter-defibrillators and pacemakers. In AF, several studies have documented the feasibility and accuracy of using sensors integrated into smartphones to detect AF and pediatric tachyarrhythmias.<sup>177–179</sup> For example, one company has developed a microchip that can be easily embedded in common cardiovascular medications to assist with medication adherence. When patients ingest medications, chips send messages to smart phones and provide caregivers and healthcare providers information to better understand patient medication-taking activities and patient response to medications. In the area of hypertension, home blood pressure monitoring has demonstrated effectiveness in identifying both masked hypertension (hypertension apparent only during home-based assessment) and white-coat hypertension (hypertension apparent only during office-based assessment).<sup>180</sup> It has also facilitated more effective blood pressure control than conventional care with the use of both pharmacist-driven Internet-based feedback<sup>181</sup> and patient self-titration.<sup>182,183</sup>

In HF, remote monitoring has generally been found to be useful and potentially cost-effective, although studies are conflicting.<sup>184</sup> For example, 5 multicenter, randomized studies of basic telemonitoring failed to improve health outcomes compared with conventional care.<sup>185–189</sup> However, the studies showed that patients were able to effectively use the technologies for home measurement of HF parameters,<sup>190</sup> suggesting that such interactions are feasible; future efforts should focus on identifying the tools that can be most useful and the methods that can optimize their potential. Taking telemonitoring one step further, there has been a wealth of research investigating implantable cardiac devices in HF that measure and transmit pulmonary or intracardiac pressures, some of which have shown significant ability to improve HF care and outcomes.<sup>191–195</sup> Furthermore, when monitoring is continuous rather than contingent on a patient activating a recording system, physicians, nurses, or even automated protocols can “learn” from these data reflecting a patient’s volume status. Finally, in the case of implant-

able cardioverter-defibrillators and pacemakers, the evidence is clear that remote monitoring of these devices is safe<sup>196–198</sup> and can even safely replace some in-person visits. Despite concerns that the use of remote monitoring might drain the battery (leading to the need for more frequent generator change procedures), it appears that the energy efficiency that can be gained via relevant programming changes minimizes any excess battery use that might occur.<sup>197,199</sup> Furthermore, remote monitoring can detect problems before they occur, preventing important outcomes such as inappropriate and appropriate implantable cardioverter-defibrillator discharges,<sup>197,200</sup> which can substantially adversely affect quality of life and lead to significant healthcare use.

Despite these examples, it is important to recognize that current gaps must be overcome before patient-reported and patient-collected data can be effectively integrated into patient care more broadly. Currently, our ability to collect patient-reported data such as symptom inventories, quality of life, and satisfaction and merge this information into the healthcare encounter in an actionable format for care delivery remains limited. For example, patient satisfaction data are often collected by systems that are independent of the LHS (eg, Avatar, Press Ganey). Tools for collecting patient-reported medical and family history, quality-of-life metrics, or care preferences can be difficult to use with large EHR systems. In addition, despite the increase in availability of wearable physiological monitors (eg, Apple Watch and Fitbit), there is currently no generalized mechanism by which these data can be imported into or leveraged in an LHS.

Although these nascent methods of collecting patient-reported information are encouraging, many have significant barriers to their sustained adoption and thus usefulness to patient engagement in the LHS. Prior work from HF telemonitoring trials describes potential barriers and may help inform solutions to optimizing the collection and use of patient-reported data.<sup>185–187,201</sup> In one trial, 45% of telemonitoring users abandoned it before the data collection period was completed.<sup>201</sup> When researchers used a qualitative approach to learn why people failed to participate or withdrew from telemonitoring studies, 3 barriers to adoption emerged.<sup>188</sup> First, patients had concerns about technical competence needed to operate equipment. When considering future needs, attention must be given to the ease of operating device equipment and applications without needing to deal with alarms and warning messages. Second, telemonitoring provoked threats to identity, independence, and self-care. Adults with cardiovascular conditions wanted to be a person with a condition, not a patient with ill health. Older adults did not want to be reminded of age, sickness, and dependence; they wanted to be personally responsible for maintaining their health and desired to be independent for as long as possible. Thus, when considering future needs related to patient engagement in LHSs, it will be

important use technology strategies, algorithms, and interactive application features that promote activation of self-care and autonomy in making decisions. Third, telemonitoring caused undesirable disruption of existing healthcare services. Patients wished to maintain and build the trusting relationships they developed with providers, and a third-party provider (information technology personnel, nurse, or electronic avatar) may disrupt or interfere with ongoing services and relationships. Such discontinuity can increase patient and family stress. Other challenges to the adoption of telemonitoring are the cost of devices and services (especially if there are monthly fees associated with monitoring), user perceptions of therapeutic effectiveness, remembering to wear/use the technology and to charge it when recharging is necessary, dealing with artifact, slow electronic processing of data, and data transfer and Internet failures.<sup>202–204</sup>

Effective remote monitoring systems will require an intuitive and reliable interface for adoption. Systems and products must be simple to use (“plug and play”) and accurate, hold value over time, enhance patient-centeredness, promote 2-way communication between patients and providers of care, and be driven by consumers. Furthermore, patients need to feel that the system or product delivers an exceptional experience, provides easy-to-understand information, and “cares” about them in some way; in the end, patients, not just providers, must derive benefit from the health information. In addition, companies developing remote monitoring devices and services meant to engage patients in care must understand that there is a gap between recording information and changing behavior.<sup>202,203</sup> Therapeutic effectiveness cannot happen if patients do not desire to monitor themselves closely, and even with close monitoring, creating enduring new habits is difficult.<sup>203</sup> Finally, mobile devices may have unintended psychological effects on patients that may influence their use.<sup>202</sup> More research is needed to learn the best strategies for creating meaningful patient engagement.

Finally, evaluation metrics are needed to determine whether the effective adoption of patient-reported information into the LHS has occurred. These metrics include both processes and outcomes. Processes might include the level of engagement of patients with health data devices, measured as general or specific use (in hours, days, weeks, or months); use when symptomatic and asymptomatic; and use for communicating with family, multiple healthcare providers, or local community agencies.<sup>174</sup> Other processes metrics might include the level of transmission of data to healthcare providers, evidence of patient-driven communication with healthcare providers, and use among patients with known low health literacy, language barriers, and history of mild cognitive decline or other social, economic, cultural, physical, or psychological barriers. Outcomes surrounding LHS information and patient engagement could include unplanned

office visits, emergency care, hospitalization, quality of life, psychological health status (anxiety or depression), social isolation, and other metrics related to quality of care and patient safety.

### Patient Preferences and Values in the LHS

Much of the efforts in patient-reported information have centered on the collection of biometric data with technology. However, collecting, understanding, and integrating patient preferences and values is an essential element of patient-reported information in the LHS. Capturing patient preference in an electronic format has many advantages. Many healthcare treatments are preference sensitive (eg, statin use in moderate-risk patients) and thus require reliable assessment and incorporation into medical decisions to provide the right care to the right patient. Incorporating patient preferences into medical decision making significantly enhances patient education and engagement with their care, which may lead to greater overall satisfaction, self-management, resilience in the face of side effects or other negative consequences of a treatment regimen, and adherence to treatment plans.<sup>205–209</sup> Furthermore, preferences are dynamic. The considerations that drive a patient’s preference for a therapy now may change over time as the patient’s circumstances and outlook evolve. An effective LHS needs to be able to account for this dynamism. Finally, attention to patient preferences can identify new areas for clinical research into the measurement, incorporation, and effect of preferences on the various methods of healthcare delivery and treatments.

Patient preferences and values also have a role in medical decision making in patients with multiple medical conditions such as many CVD patients. There have been recent calls for shifting the orientation of healthcare delivery away from a disease-centered construct to a patient goals-centered one.<sup>210</sup> Doing so would require elicitation of patient goals for their health and the workload necessary to achieve it. For example, patients would need to specify goals for functional status, symptom burden, life prolongation (often linked to specific life events, eg, to see a child get married), well-being, and ability to fulfill occupational or social roles. Patients and their providers would then need to integrate these goals with the workload required to achieve them such as medication management, self-management tasks (eg, physical therapy, monitoring blood pressure and weight), healthcare use, procedures, and costs. Although the effort required to determine preferences and to design individualized care plans would be significant, preliminary studies indicate that patients are more likely to identify realistic goals after such a process and may achieve better subsequent health outcomes.<sup>211</sup> A patient-centered goal-identification approach is especially beneficial for patients with multiple comorbidities because disease-

centered recommendations can often conflict with other disease-centered guidelines. Incorporating patient goals assessment into patient decision making can identify which of the relevant clinical guideline recommendations are in line with the patient's goals and potentially minimize conflicts.

There have been some preliminary efforts to incorporate patient goals and quality-of-life measures into an overall framework of care. Notably, the Oregon Health Plan, which provides benefits for Medicaid beneficiaries in that state, assigned coverage for conditions based, in part, on treatments that would contribute meaningfully to patients' quality of life.<sup>212</sup> However, this plan is a rare example of systematic integration of patient goals such as quality of life into healthcare decisions but has had some difficulty in execution.

Integrating patient preferences and values into LHS processes has a variety of challenges. Significant issues in measurement of patient preferences and values exist.<sup>213</sup> These concepts are highly personal, and understanding the best methods for assessing them to allow both comparisons with other patients and medical decision making is needed. Like health status, preferences and values would need ongoing monitoring and updating to account for their dynamic nature. Furthermore, integration of preferences that account for all medical conditions and decisions applicable to a given patient must be developed, rather than simply a focus on a single condition. Finally, evaluation of the best methods that use patient preferences in care decisions and their effects on decisional quality, patient satisfaction, and health outcomes is needed.

### Patient Engagement With the LHS

Once patient preferences and values are known, the LHS needs to provide effective methods of integrating this information and engaging patients in their care. Patient engagement innovations have been stimulated by research demonstrating that many treatment decisions are poorly aligned with patients' goals, values, and preferences for surgical or procedural innovations<sup>214,215</sup> or end-of-life care.<sup>216</sup> As a result, there has been early, but promising, work in the area of incorporating patient education and preferences into shared medical decision making (SDM) in cardiac disease. SDM is a collaborative process that allows patients and their providers to make healthcare decisions together, combining the best scientific evidence available with the individual patient's values and preferences. For example, investigators at the Mayo Clinic piloted a statin choice decision aid that resulted in better patient understanding and statin adherence rates.<sup>217</sup> Similarly, SDM work has occurred in the use of left ventricular assist devices in end-stage HF. Investigators developed a left ventricular assist device decision aid that accurately characterized the multiple consider-

ations patients face when contemplating a highly invasive procedure for a life-threatening illness that is now undergoing acceptability testing.<sup>218,219</sup> Finally, a number of SDM tools focused on CVD care have been developed and tested in the emergency department, inpatient, and ambulatory settings.<sup>213,220,221</sup> Existing tools include decision aids for management of acute chest pain, hyperlipidemia, hypertension, AF, coronary heart disease, and congestive HF; however, although many tools have been developed and tested locally, the broader implementation of these innovations into routine clinical practice has been limited.<sup>220</sup>

To spread these innovations broadly, the Center for Medicare & Medicaid Innovations has funded a number of grants to implement SDM. For example, the Center for Medicare & Medicaid Innovations released the Million Heart Cardiovascular Risk Reduction model to test the effect of financially incentivizing providers to engage patients in SDM for cardiovascular risk reduction.<sup>221</sup> This will be operationalized through providing individualized cardiovascular risk to each patient and the benefits of risk reduction strategies such as controlling blood pressure, taking daily aspirin, and stopping smoking. This program has the potential to make cardiovascular innovations for SDM a reality for everyday practice and to allow patients to be engaged in decisions about their care.

### LHS INCENTIVES AND CULTURE

Technology and data are necessary components of the LHS. However, they are insufficient to achieve the sustained and institutionalized improvements that bring about true value in the LHS. An effective healthcare system is ultimately dependent on the people who make up that system, people who have all the strengths and weaknesses that are part of human nature. Thus, a successful LHS is one that harnesses the strengths and redirects the weaknesses so that each individual and the system as a whole achieve their maximum potential. The LHS must overcome the comfort of established approaches to care, historical organizational silos, competing motivations and priorities, and cognitive biases that impede continuous performance improvement. Thus, aligned incentives and a culture of continuous learning with strong leadership are necessary to channel the power of individuals to create the LHS. In this section, we describe how the current incentive structure, particularly in regard to reimbursement, affects the LHS. In addition, we describe the cultural and leadership elements necessary to execute and sustain the LHS.

### Incentives

A popular adage in the healthcare improvement world is that "every system is perfectly designed to get the re-

sults it gets.”<sup>222</sup> Accordingly, if incentives are not aligned with continuous and informed improvement, the LHS is impossible. For example, in 1996, the National Committee for Quality Assurance established a performance measure based on rates of prescribing  $\beta$ -blockers for patients after a myocardial infarction, which employers could use to select health plans for their employees. With  $\beta$ -blocker use now directly linked to incentives such as market forces and public reporting, healthcare providers focused on improving  $\beta$ -blocker prescription rates, often using the data-driven process improvement strategies inherent in the LHS. By 2007, the use of  $\beta$ -blockers after acute myocardial infarction had reached such consistently high levels that the  $\beta$ -blocker performance measure was retired and no longer used to evaluate managed care plans.<sup>223</sup> Although the lack of a control group and other design aspects of this program limit our ability to fully understand the specific incentives that drove the improvements in  $\beta$ -blocker use, its overall impact provides a useful example of how incentives can affect the LHS.

Lessons from this example and others fueled many of the healthcare reforms of the 2010 Affordable Care Act and its focus on value-based reimbursement. With the subsequent passage of the Medicare Access and CHIP Reauthorization Act, which expanded the financial reach of Medicare’s value-based purchasing programs and alternative payment models such as accountable care organizations, reimbursement is becoming more aligned with performance, resulting in more focus on data-driven continuous learning approaches to evaluate and improve care. In CVD, one prominent example of this strategy is the previously described Million Hearts Model, which reimburses practices for reducing the aggregate cardiac risk of their patients at highest risk for developing atherosclerotic CVD.<sup>221</sup> As a result, it is expected that practices will deploy targeted process improvement strategies to target and treat these patients.

Incentive programs such as these are an essential component of the organizational development of the LHS. Going forward, a challenge within these systems will be making the incentives broadly applicable to providers and other participants within the system. Questions of how much, to whom, and in what ways incentives are distributed will greatly affect how much buy-in there is among physicians, nurses, and front-line staff. Successful organizations will be ones that use the best approaches to align incentives, at all levels, with the objectives of using continuous learning to inform high-quality organizational performance.

## Culture

The concepts of leadership and culture are intertwined because leadership plays a major role in setting an organization’s culture by establishing the mission, vision,

and values and, perhaps more important, by selecting the type of people who will work in the organization. In aiming for a culture supportive of a LHS, certain enabling features stand out. Bradley and colleagues<sup>224</sup> examined the factors associated with hospitals’ success in providing  $\beta$ -blockers after acute myocardial infarction. Four factors associated with better hospital performance were shared goals for improvement, substantial administrative support, strong physician leadership, and the use of credible data feedback. All 4 elements are consistent with a LHS.

As organizations seek to institutionalize continuous process improvement and simultaneously support research, one challenging cultural element is the different data needs and evaluation approaches between clinical operations teams and research teams. Clinical quality improvement teams implement rapid-cycle changes that have practical uses of available data and that address current clinical needs as quickly as possible. On the other hand, research teams seek greater standardization and rigor for their data and analysis, often taking many months to complete their projects. The LHS must sit somewhere in between, effectively generating research insights at operational speed. In a National Cancer Policy Forum of the Institute of Medicine workshop, presenters concluded by stating, “In generating evidence through a rapid-learning system, it is important to match study design with the importance and complexity of the research question, balancing rigor against the need to generate timely generalizable evidence.”<sup>225</sup> A successful LHS will merge quality improvement and research cultures such that both groups achieve their respective goals and achieve a comfort level with the ongoing use of data and evaluation.

## Leadership

In their book *On the Mend: Revolutionizing Healthcare to Save Lives and Transform the Industry*, Toussaint and Gerard<sup>226</sup> describe how the ThedaCare healthcare system “learned that every medical act is a series of steps that can be examined and improved.” Starting with strong executive leadership led by Chief Executive Officer Toussaint, they created a system that incorporated iterative cycles of performance improvement, resulting in remarkable results for patients. For example, using data to inform transformation, ThedaCare improved its coronary artery bypass surgery mortality rate from  $\approx 4\%$  to almost zero, decreased surgical length of stay from 6.3 to 4.9 days, and decreased costs by 22%. It is important to note that this improvement did not occur overnight. Rather, it took 7 years and required strong leaders at every level of the organization.

One important aspect of leadership is the top of an organizational hierarchy with its governing board members and managing officers. The board sets the mis-

**Table 2. LHS Action Steps and Evidence of Success by LHS Domain and Specific Component**

LHS Domains	Specific Component	Action Steps	Evidence of Success
Science and informatics	EHRs	Create standardized data models, data dictionaries, and data storage protocols (OMOP common data model, etc)	Data cross multiple healthcare settings in an interpretable and actionable format
		Increase interoperability of health data exchange	Patient-reported data and other health-related data are incorporated into the EHR and are part of decision making
		Collect and incorporate multiple data sources into EHR data	
		Improve data completeness and quality	EHR data are of research-grade quality
	Clinical registries	Integrate registry data collection in clinical workflow (eg, EHR vendors develop templates to automatically populate NCDR registries with EHR data)	Data are entered once via the EHR and then used to populate registries
		Link EHR, claims, and other data sources	Clinical registry data are of research-grade quality
		Improve data completeness and quality	
	Alternative data sources	Identify health-relevant data sources for collection and incorporation (eg, air pollution data)	Clinical assessment and care integrate traditional healthcare system information with relevant and complementary environmental and patient-reported information
		Develop robust methods of collecting patient-reported outcomes (eg, patient health status as outlined by ICHOM)	
		Develop actionable insights from the combination of traditional and alternative data sources (eg, restricting outdoor activities in patients with HF during high-pollution days)	Data are automatically transferred to the EHR to be available for clinical action and research
		Improve collection methods of semistructured and unstructured health-related data (eg, using NLP and other collection methods)	
	Data oversight	Articulate data use goals for LHS purposes	All participants in LHS understand the mission of data collection and use
		Create a data oversight team that reviews data for accuracy, completeness, currency (based on national guidelines), and value to stakeholders	Data security and privacy are clear and consistent across multiple use cases
		Review and unify patient privacy regulations for data use in both clinical performance and research activities	Data regulation does not impede generating insights “at operational speed”
		Identify effective methods for healthcare provider input of data needs and issues	Data are trustworthy when used in clinical performance and research activities
	Predictive analytics	Develop reliable prediction models that balance accuracy with generalizability (eg, likelihood of HF readmission)	Predictive models will be incorporated into clinical workflow, supporting risk prediction for individuals and populations, and aligned with clinical actions in response
		Develop and validate advanced data mining methods (eg, machine learning) to enhance model performance	
		Validate models over time, incorporating longitudinal, dynamic data to account for real-time population and treatment changes	Predictive models will improve patient safety by anticipating adverse clinical events with sufficient accuracy and timeliness to allow meaningful action
		Develop optimal model output visualization and integration into clinical workflow	
	CDS	Develop effective CDS tools that properly apply relevant evidence to appropriate patients and populations (eg, assessment of appropriate discharge medications in post-MI patients)	CDS tools are integrated with clinical data to generate actionable insights for the right patient at the right time
		Optimally integrate CDS tools in clinical workflows with the appropriate patients and management questions	CDS tools are updated in a timely fashion as evidence evolves
		Evaluate CDS-assisted decisions on patient outcomes	

(Continued)

**Table 2. Continued**

LHS Domains	Specific Component	Action Steps	Evidence of Success
Science and informatics Continued	QI and healthcare delivery evaluation	Develop sufficient and relevant data elements to monitor and evaluate QI efforts	Guided by real-time clinical data, QI efforts are designed, implemented, tested, and embedded in an ongoing fashion
		Establish QI teams and processes to support rapid QI projects	
		Develop mechanisms to implement successful QI efforts into sustainable clinical operations and deimplement inferior clinical processes	Clinical processes are continually evaluated for optimal performance and, if not optimal, replaced with processes that are empirically proven to be superior
	Clinical trials and minimal-risk, prospective, noncomparative, clinical research	Organize EHR data to allow effective cohort identification for clinical trial enrollment (eg, enrollment in the ADAPTABLE trial)	Clinical trial participant identification, consent, and randomization are embedded at the point-of-care with EHR and other clinical data
		Organize EHR data to support data collection efforts during the conduct of clinical trials	Data elements collected during routine care are of sufficient quality to simultaneously populate clinical trial case report forms
		Develop point-of-care patient consent and randomization protocols	
Patient-clinician partnerships	Patient-reported information	Use validated, reliable tools or develop reliable tools that are sensitive to measuring change over time	Patient-reported information is consistently collected and incorporated into clinical management
		Develop acceptable user interfaces and uptake to collect patient symptoms, quality of life, and other patient-centered information	
		Incorporate patient-reported information into clinical workflow to provide actionable insights	
		Develop data infrastructure that can handle patient wearables or other remote data source and incorporate into other health-related data	
		Demonstrate the incremental benefit of patient-reported information on health outcomes	
	Patient values and preferences	Determine best methods of assessing patient values and preferences with respect to health and healthcare decisions	Patient values and preferences are systematically gathered and periodically updated
		Determine methods of incorporating patient values and preferences into clinical decision making	Values and preferences are incorporated into SDM discussions and tools, particularly in preference-sensitive scenarios
	Patient use of LHS information	Determine the best methods of presenting LHS data to patients in an understandable and usable format (eg, Mayo Clinic's Statin Choice Decision Aid)	Patients will engage with their health data to understand their health, care management, and personal actions that support it
		Develop patient educational and engagement tools that facilitate healthy behaviors and decisions	Patients will engage with the healthcare system to provide input on clinical and research matters
		Identify effective methods for patient input on clinical decisions, healthcare delivery processes, and research questions	
Leadership, culture, and incentives	Leadership	Identify leadership practices that are associated with supporting LHS development, execution, upkeep, and expansion	Leaders will define and support LHS concepts as a fundamental governing philosophy for healthcare systems
	Culture	Identify cultural components of systems that facilitate or impede an orientation toward continuous learning	Healthcare systems will create and sustain a culture of continual inquiry, clinical excellence, and new evidence generation
		Determine best methods of transmitting and supporting culture components to support LHS	
		Determine best methods of engaging participants in healthcare systems to contribute to and grow a LHS culture	

(Continued)

**Table 2.** Continued

LHS Domains	Specific Component	Action Steps	Evidence of Success
Leadership, culture, and incentives Continued	Incentives	Identify nonmonetary incentives (eg, public reporting) that align with improved clinical performance and minimal deleterious unintended consequences	Nonmonetary and monetary incentives will provide positive motivation to support the concepts of LHS
		Assess the impact of reimbursement and other monetary-based incentives on clinical performance and continuous inquiry by LHS	Data collection efforts will monitor for negative, unintended consequences of incentive programs

ADAPTABLE indicates Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness; CDS, clinical decision support; EHR, electronic health record; HF, heart failure; ICHOM, International Consortium of Health Outcomes Measurement; LHS, learning healthcare system; MI, myocardial infarction; NCDR, National Cardiovascular Data Registry; NLP, natural language processing; OMOP, Observational Medical Outcomes Partnership; QI, quality improvement; and SDM, shared decision making.

sion, vision, values, and strategy that guide decisions throughout the organizations, both big and small.<sup>227</sup> These principles can translate to higher-performing healthcare organizations. For instance, in a recent study, hospitals with boards who had greater experience in quality had higher-performing management and better quality of care.<sup>228</sup>

However, leaders at all levels of the organization, not just the top, are critical to achieving an LHS. For example, leadership is often found with front-line employees of an organization, who may or may not hold formal management positions. An example might be a unit clerk who keeps track of patient complaints and uses that information to identify a problem and implement a solution. Thus, senior leadership must partner with these front-line leaders in examining current practices and outcomes, changing care delivery, evaluating the results, and translating improvements into sustained activities. A foundational step to ensure that leaders throughout the organization are prepared for ongoing quality improvement is the appropriate training of middle managers. For example, Kaiser Permanente healthcare system middle managers undergo a 2-day interactive training session on patient safety that uses a continuous learning cycle of identifying and mitigating safety risks, redesigning care, and preventing failures. In this manager training, Kaiser instills the mindset that “learning and making changes to minimize the chance of errors are the norm, not the exception.”<sup>229</sup>

Another approach to activating leaders at all organizational levels is a technique known as rounding to influence. In this method, senior leaders use data to identify a target for improvement and then round regularly with front-line staff using real-time patients and an interactive approach to educate staff about a clinical problem, to learn from those staff members about barriers to improvement, and to collectively address barriers and implement change.<sup>230</sup> Through these rounds, data-driven patient care problems are addressed at the point of care, with clinical staff working with senior leadership to learn from one another and achieve quality improvements.

## CONCLUSIONS

The potential for LHSs to improve the quality and efficiency of health care is great. By attending to and developing each of the domains identified above—science and informatics, patient-clinician partnerships, incentives, and culture—information and action can be generated to drive continuous learning, clinical excellence, optimal healthcare delivery, and new evidence generation. In cardiovascular care, multiple examples of the various domains exist and underscore the potential for this area of medical care to serve as a powerful learning laboratory for how LHSs can be created, implemented, and sustained. Nonetheless, much work remains to be done. Table 2 outlines the next steps in each of the domains of an LHS, provides a picture of what success would look like, and summarizes representative examples. The hope of this writing committee is that these and other steps will provide a useful road map for continued movement toward functional and vibrant LHSs in cardiovascular care and, by extension, other aspects of health care. The informational, moral, and financial imperatives that motivated the Institute of Medicine report *Best Care at Lower Cost: The Path to Continuously Learning Health Care in America*<sup>2</sup> are even more pressing today, and our collective responsibility is to deliver the LHS that meets the challenge.

## FOOTNOTES

The American Heart Association makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the writing panel. Specifically, all members of the writing group are required to complete and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest.

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## DISCLOSURES

### Writing Group Disclosures

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This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (a) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (b) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

\*Modest.

†Significant.

††Now employed at American College of Cardiology.

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\*Modest.

†Significant.

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## The Learning Healthcare System and Cardiovascular Care: A Scientific Statement From the American Heart Association

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