JACC SCIENTIFIC STATEMENT

Remote Monitoring for Heart Failure Management at Home

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ABSTRACT

Early telemonitoring of weights and symptoms did not decrease heart failure hospitalizations but helped identify steps toward effective monitoring programs. A signal that is accurate and actionable with response kinetics for early re-assessment is required for the treatment of patients at high risk, while signal specifications differ for surveillance of low-risk patients. Tracking of congestion with cardiac filling pressures or lung water content has shown most impact to decrease hospitalizations, while multiparameter scores from implanted rhythm devices have identified patients at increased risk. Algorithms require better personalization of signal thresholds and interventions. The COVID-19 epidemic accelerated transition to remote care away from clinics, preparing for new digital health care platforms to accommodate multiple technologies and empower patients. Addressing inequities will require bridging the digital divide and the deep gap in access to HF care teams, who will not be replaced by technology but by care teams who can embrace it. (J Am Coll Cardiol 2023;81:2272–2291) © 2023 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Heart failure (HF) affects >7.5 million people in North America. Despite progressive improvement in outcomes with neurohormonal and device therapies for heart failure with reduced ejection fraction (HFrEF), patients hospitalized still take home a 50% risk for rehospitalization in the next 6 months, and they carry symptom burdens that undermine quality of life and perception of control over their condition. These burdens of HFrEF are shared by patients with heart failure with preserved ejection fraction (HFpEF), who now represent more than one-half of our heart failure hospitalizations (HFH) and derive only limited benefit from the therapies that have been so effective to decrease HFH with HFrEF.

This presentation will review how the neutral trials of early telemonitoring have directed attention to the fundamental components of effective heart failure management (HFM), including the pathophysiology behind relevant monitoring signals, the development of personalized algorithms, and the circles of connected care. The role of COVID-19 is shown to have accelerated the transition away from clinic-based care to the home and to have enhanced recognition of inequities of care. With emerging monitoring and response strategies, enhanced by machine learning and artificial intelligence (AI), digital health care will play a vital role while presenting challenges for integration and validation. A variety of digital health care platforms will be needed to bridge the digital

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HIGHLIGHTS

- Remote monitoring coupled with a system of care that engages, informs, and empowers patients is essential for effective home management of HF to control symptoms, avoid hospitalization, and ameliorate the patient's perception of illness.

- Effective remote monitoring requires an accurate, reliable signal that is actionable through personalized algorithms.

- Evolving digital health care must address the digital divide and deep gaps in access to HF management.

define signal thresholds and link them to therapeutic intervention; and intersecting circles of the multidisciplinary team to connect to patients and respond to remote monitoring data, as shown in the **Central Illustration**.

TRACKING PROGRESSION TO HF EVENTS.

The progression to hospitalization has been studied primarily after prior HFH. Adjudication of HF events in clinical trials requires signs and symptoms of congestion and treatment with intravenous diuretic agents for decongestion. Congestion without clinical hypoperfusion dominates the "wet and warm" profile, identified in >90% of HF hospitalizations.[8] The initial goal of HFH is decongestion, without which patients characterized as "wet and sent home" have almost twice as many readmissions.[9] However, even after discharge free of congestion, orthodema recurred in 65% of patients within 3 months in the NHLBI (National Heart, Lung, and Blood Institute) HF network trials,[10] and one-half of patients required a doubling of diuretic agent dose during the first 4 to 8 weeks after discharge with or without sacubitril/valsartan.[11] Cleland and Pellicori[12] have emphasized, "To master heart failure, first master congestion."

Early Lessons From Ambulatory Monitoring. Although symptoms are often perceived suddenly, there is a consistent pattern of slowly rising cardiac filling pressures for about 4 weeks before HFH with HFrEF and about 3 weeks for HFpEF, as described by Zile et al.[13] This progressive elevation has been remarkably parallel for different cardiac pressures from different devices (**Figure 1**). The pulmonary artery (PA) pressures peak at HFH, decrease within hours during diuresis in the hospital, and generally fall to baseline or below by hospital discharge.[14] By contrast, filling pressures generally do not rise in patients who are not hospitalized or are hospitalized for non-HF causes. Lung congestion itself can also be detected by thoracic bioimpedance early during progression of congestion, often 2 to 3 weeks before HF events.[15] Return of lung impedance to baseline is delayed, often by a week or more after hospital discharge.[16]

Remote cardiac pressure monitoring has diminished some of the mystery about the "why" and "when" of decompensation, once believed to be inevitable. Routine monitoring often reveals increases in filling pressures within 24 to 48 hours of identifiable triggers such as missed diuretic

divide and to support greater access to HF care teams for all patients with HF.

HF DISEASE MANAGEMENT IN EVOLUTION

In a landmark study from 1995, Rich et al[1] demonstrated >50% reduction in HFH for elderly patients in a randomized trial of multidisciplinary care after discharge. The benefit of multidisciplinary HF care was recognized also in transplantation programs, with a 35% decline in HFH at 6 months for patients not undergoing transplantation, described by Fonarow et al[2] and seen also in clinical research trials. A systematic international review by McAlister et al[3] in 2004 confirmed consistent benefit of specialized HF team management to decrease HFH. However, rates of hospitalization and mortality still remained high.

EARLY TELEMONITORING TRIALS. Telemonitoring was introduced with the hope of decreasing decompensation at home and stretching the capacity of HF clinic staff to manage growing caseloads. Although promising in small studies, combinations of structured support and telephone transmission of weights, vital signs, and symptoms consistently failed to demonstrate benefits in large randomized trials (**Table 1**).[4-6] A recent meta-analysis of 10,981 patients from 29 trials was large enough to show significant but modest and variable benefit of this type of telemonitoring to reduce HFH and improve quality of life.[7]

COMPONENTS OF EFFECTIVE MONITORING TO DECREASE HOSPITALIZATION. The early trials highlighted what is needed for remote monitoring to effectively decrease HFH: dynamic signals that reflect the physiology of decompensation; algorithms that

TABLE 1 Examples of Signal Types for Remote Monitoring

Type of Signal	Specific Product	Patient Site	Representative Trials (Year)	Impact on Heart Failure Hospitalizations
Weights, vital signs, and other				
Traditional telemonitoring with combinations of weights, vital signs, reported symptoms + rhythm strips	Various	Home	TELE-HF (2010)[4] BEAT-HF (2016)[6] TIM-HF I (2010)[5] TIM-HF II (2018)[79]	No benefit No benefit, small signal for better quality of life No benefit Benefit for mortality with 24/7 emergency medical HF phone access
Fluid in the lung				
Thoracic impedance with Impedance cardiography	BioZ	Clinic Hospital	PREDICT (2006)[43] BIG substudy of ESCAPE (2009)[44]	Predictive of outcomes in clinic outpatients Poor correlation with hemodynamics or outcomes for inpatients
Thoracic impedance with ICD	OptiVol OptiVol or CorVue	Home	DOT HF (2011)[41] OptiLink-HF (2016)[119] MORE-CARE (2017)[120] LIMIT-CHF (2016)[121]	Alerts increased patient visits with no decrease in HF hospitalizations More HF hospitalizations with intervention than in control No benefit
Thoracic impedance and other measures from ICD		Home	IN TIME (2014)[122]	No benefit
Thoracic impedance with ICD		Home	EVOLVO (2012)[123]	No benefit
Remote dielectric sensing of lung water (ReDS)	Sensivest	Home Hospital before discharge	SMILE trial (2016)[49] ReDS-pilot SAFE-HF (2021)[47]	Validated against CT measured lung water content Preliminary results in discharged patients showed reduction in HFH with ReDS when managed per protocol Pilot trial before discharge showing 32% needed further diuresis
Radiofrequency sensor: wearable patch on chest	Microcor	Home	BMAD Trial (2023)[50]	Pair of single-arm trials suggesting decreased HFH using patch to guide therapy
Hemodynamic pressure monitoring				
PA pressure monitor	CardioMEMS	Home	CHAMPION (2011)[32] GUIDE-HF (2021)[20,33] Nonrandomized 2,000 Medicare patients (2017)[37] 234 Europe-MEMS (2020)[38] FDA Postapproval U.S. 1,200 patients (2023)[37]	Benefit for HFH and total hospitalizations, QOL Benefit in prespecified pre-Covid 19 analysis Compared with preimplantation: Benefit to reduce PA pressures and HF hospitalizations at 6 months Benefit to reduce PA pressures and HF hospitalizations at 1 year Sustained reduction in PA pressures and HF hospitalizations over 2 years
LA lead for pressure monitoring enabled for self-management with personalized algorithm	HeartPOD monitor alone or with CRTD	Home	LAPTOP (2016)[34,124]	Benefit to reduce HFH was comparable to CHAMPION trial discontinued because of complications of device insertion across septum
LA pressure monitoring tube anchored across atrial septum	V-LAP	Home	VECTOR-HF(2022)[36]	Correlates with pulmonary wedge pressure at 3 months
PA pressure data integrated with HF package of vital signs and symptoms	Cordella with Heart Failure System	Home	PROACTIVE-HF III[75]	450 patients in PROACTIVE class III—ongoing follow-up
Multiparameter scores with rhythm devices				
ICD with impedance,[a] heart rate and variability, activity		Home	Cowie (2013)[53] REM-HF (2017)[54]	High risk score conferred 10X risk for events compared with low risk Remote monitoring to guide therapy had no impact to decrease HFH or death
ICD with impedance,[a] minute ventilation, activity		Home	CLEPSYDRA (2014)[125]	Alert score with 34% sensitivity False-positive rate of 2.4 alerts per patient-year
CRTD with impedance, HR, RR, activity, and heart sounds	HeartLogic	Home	MultiSENSE Trial (2017)[56] (2018)[57]	Alert score validated with 70% sensitivity, specificity 85.7% Alert zone conferred 10X risk of HF event.
CRTD or ICD with impedance, HR + HRV, atrial arrhythmias and PVCs, activity		Home	SELENE-HF (2022)[58]	Alert score with sensitivity of 65.5%; false-positive rate of 0.7/patient-year Improved by adding Seattle HF Model score before device implantation
CRTD and ICD with impedance, HR, HRV, arrhythmias, pacing		Home Early after discharge	TRIAGE-HF (2018)[126] (2023)[16]	Risk metric became predictive 60 days before HF event, continued rising until discharge Fell by a week after discharge in patients with low risk of readmission
Example of multiparameter wearable technology				
LINK HF	Multisensor Health Patch	Hospital to Home	LINK-HF (2020)[127]	Multivariate physiological telemetry from a wearable sensor can provide early detection of impending rehospitalization

[a]Impedance refers to thoracic impedance.
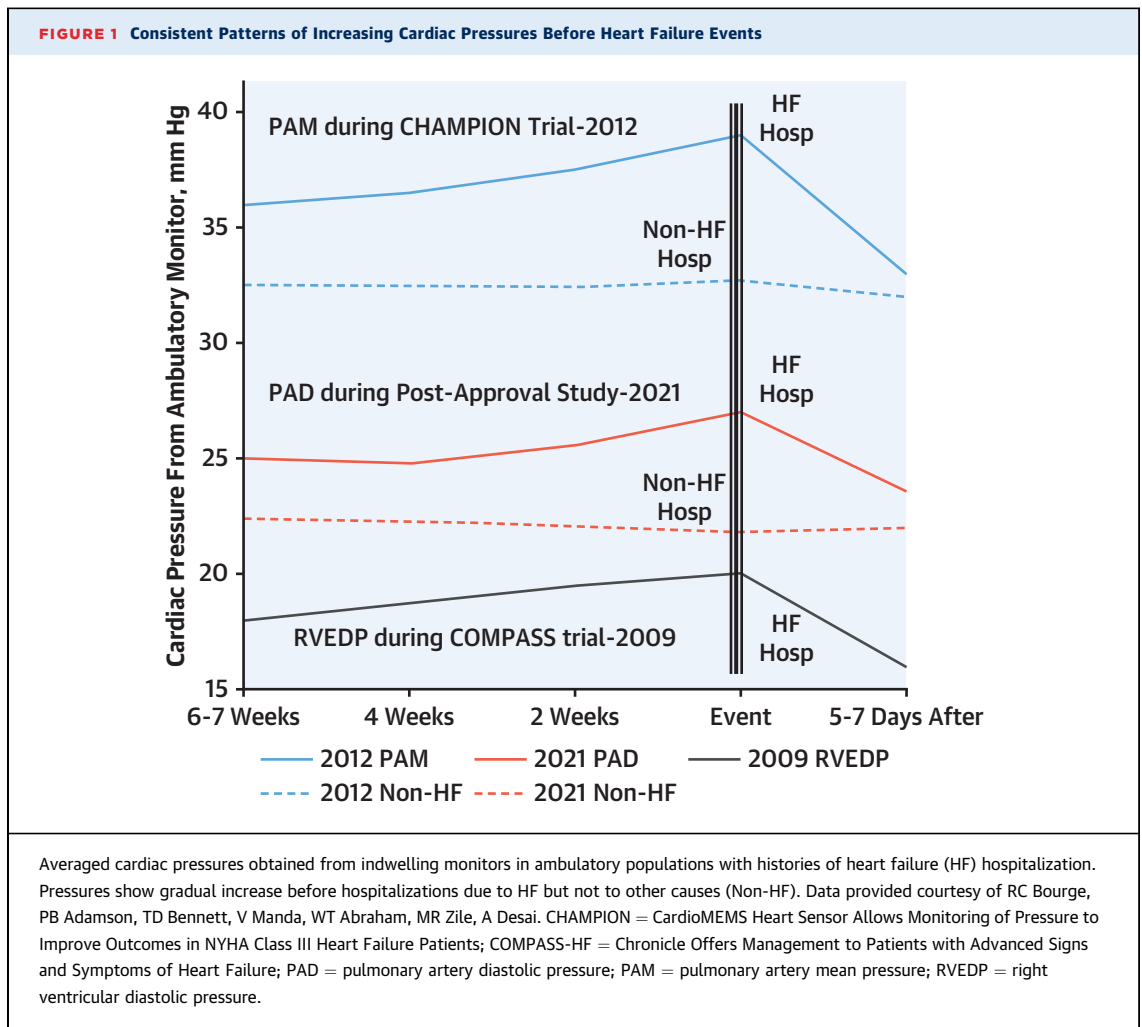
CRTD = cardiac resynchronization therapy defibrillator; HF = heart failure; HFH = heart failure hospitalizations; HR = heart rate; HRV = heart rate variability; ICD = implantable cardioverter-defibrillator; LA = left atrium; PA = pulmonary artery; PAD = pulmonary artery diastolic pressure; PVC = premature ventricular complexes; ReDS = remote dielectric sensing; RR = respiratory rate.

CENTRAL ILLUSTRATION Connecting the Circles Between Clinic and Home

Stevenson LW, et al. J Am Coll Cardiol. 2023;81(23):2272–2291.

Demonstration of the fundamental components of heart failure management (HFM) to include the signal for transmission and early re-look, algorithms to guide response, and the supervising clinical teams. The direct loop provides immediate response to the patient based on personalized algorithms, and the mediated response occurs after data go to the care team for analysis. Provisions must be made for staff response to the less frequent but urgent alerts from transmitted data (fourth-level response), and to 24/7 emergency calls directly from patients.

agent doses or heavy salt intake in salt-sensitive patients, both particularly common on weekends and holidays (**Figure 2**). Arrhythmias and viral infections also can trigger progressive increases in PA pressures.

Dynamic Volume Compartments. Fluid can shift rapidly between the intravascular and recruitable fluid compartments, influenced by sympathetic tone.[17,18] The fluid from the splanchnic circulation can expand the intravascular volume by about 2 L, as measured by radionuclide volume distribution studies. This recruitment may be sufficient to

precipitate truly acute pulmonary edema during a hypertensive crisis or critical valve stenosis. However, it would not be adequate to explain slow progression to typical HF hospitalizations, usually associated with extravascular fluid accumulation in lungs, legs, or abdomen. The average net diuresis by discharge in the NHLBI heart failure network trials was 5 to 7 kg, which suggests net fluid accumulation rather than redistribution alone.[10] However, cardiac filling pressures remain a dynamic function involving diastolic function and vascular tone as well as circulating volume.

FIGURE 1   Consistent Patterns of Increasing Cardiac Pressures Before Heart Failure Events

Averaged cardiac pressures obtained from indwelling monitors in ambulatory populations with histories of heart failure (HF) hospitalization. Pressures show gradual increase before hospitalizations due to HF but not to other causes (Non-HF). Data provided courtesy of RC Bourge, PB Adamson, TD Bennett, V Manda, WT Abraham, MR Zile, A Desai. CHAMPION = CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients; COMPASS-HF = Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure; PAD = pulmonary artery diastolic pressure; PAM = pulmonary artery mean pressure; RVEDP = right ventricular diastolic pressure.

The specific role of the kidney is not well understood among the causes and consequences of progressive elevation of filling pressures before HFH. In an elegant study of 80 patients with chronic HF, the first morning urine sampling showed general stability of urinary sodium excretion until a marked decline within a couple of days before HFH, with rapid recovery to baseline after decongestion. In this study, as in other studies of close HF monitoring, weights and symptoms did not change detectably until just before decompensation, if at all.[19]

Cardiac Output During Decompensation. Right-heart catheterization at the time of monitor implantation has shown that cardiac indices are frequently much lower than expected, regardless of New York Heart Association functional class.[20,21] However, the prevalence of the clinical "wet and cold" profile during HFH has been low,[8] although it may be increasing with better outpatient management of congestion. We do not currently have reliable information about perfusion as a congestion episode develops. However, when we can better monitor indices such as cardiac output, mixed venous oxygen saturation, or peripheral tissue perfusion in ambulatory patients, we will learn when they contribute to decompensation. Even with information about ambulatory indices of hypoperfusion, it may not currently be actionable in the ambulatory setting unless therapies such as digoxin or omecamtiv[22] might be shown to improve both perfusion and clinical outcomes.

Sympathetic Activation. Sympathetic activation occurs early in HFrEF and plays a major role in disease progression. Decreases in cardiac output and blood pressure decrease high-pressure baroreceptor firing, which then leads to increased sympathetic outflow from the nucleus tractus solitarius. However, cardiac norepinephrine release is also triggered by elevated left ventricular end-diastolic pressures and decreased by reductions in filling pressures.[23]

FIGURE 2 Holiday Monitoring of Pulmonary Artery Pressures
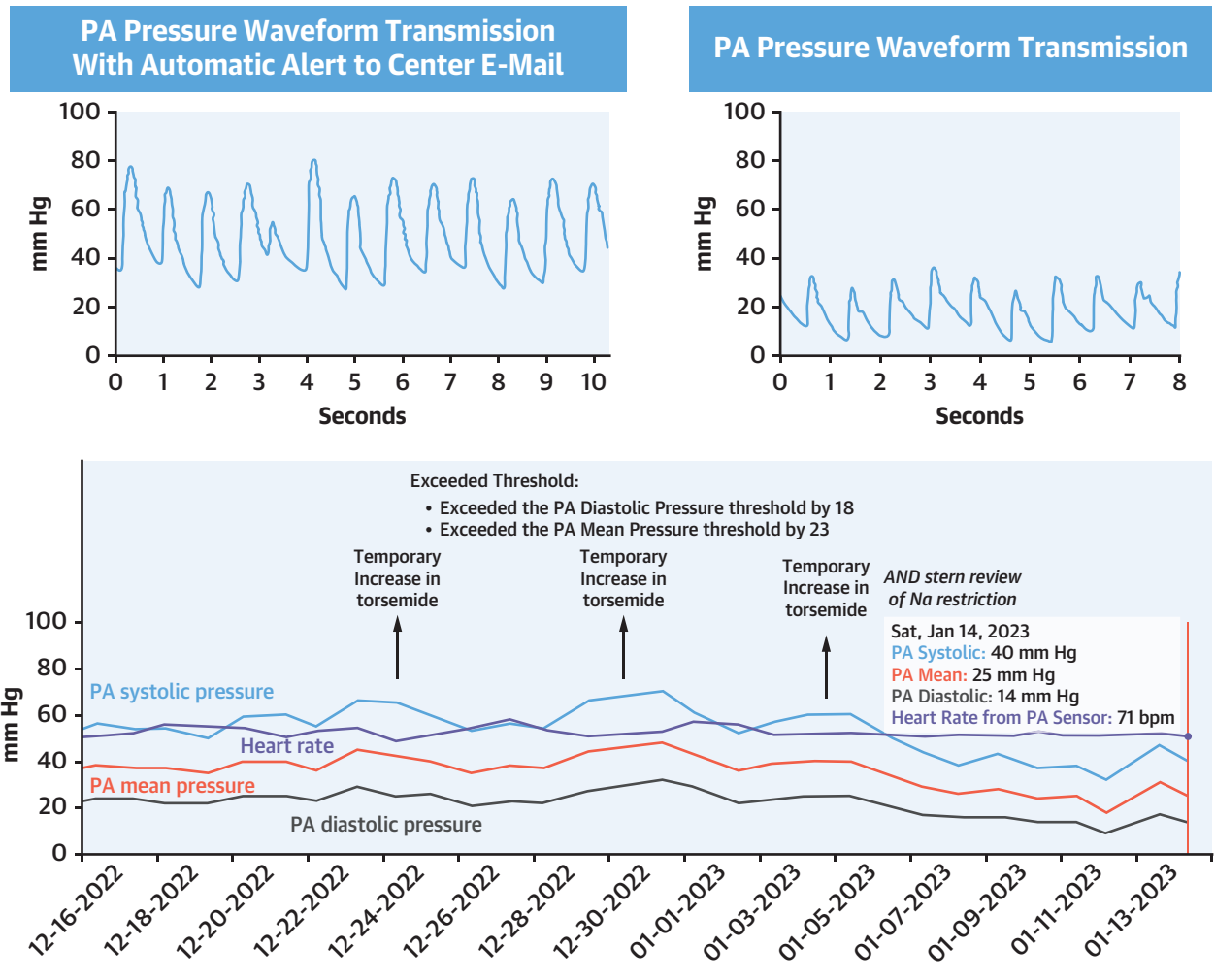
Ambulatory monitoring in a 64-year-old man 4 years after implantation of a pulmonary artery (PA) pressure monitor for pulmonary hypertension with left ventricular failure from valvular heart disease. During the winter holidays, each PA pressure elevation episode decreased briefly after increased diuretic agents, but the reduction was sustained after the dedicated program nurse delivered a stern re-education about salt restriction.

Heart rate elevation is a common indication of sympathetic activation. When it is monitored continuously by implanted rhythm devices, heart rate, particularly nocturnal, has frequently been shown to increase many days before HFH.[16] Heart rate variability also decreases, in part related to increased respiratory rate. Heart rate elevations as harbingers of decompensation may be blunted by β-blockers, antiarrhythmic therapies, and pacemaker dependence. Unlike cardiac filling pressures, heart rate and heart rate variability do not return to baseline until days after hospital discharge, limiting these signals for tracking acute changes during therapy.[16]

There is less demonstrable sympathetic activation in chronic HFpEF than in HFrEF.[24] For HFpEF as well as for HFrEF, there is evidence that elevated cardiac filling pressures are associated with elevated sympathetic tone.[25] It has not been established how sympathetic activation as evidenced by changes in heart rate parameters may track with early worsening of congestion specifically in HFpEF.

CHOOSING SIGNALS FOR REMOTE PATIENT MONITORING

WHAT IS THE INTENDED ROLE OF MONITORING?
Most investigations with remote hemodynamic

monitoring have focused on patients who have had HFH and remain at high risk for decompensation, needing frequent intervention to avoid recongestion (Table 2). Multiple different device types have been studied (Figure 3). Abraham et al[26] have suggested that requirements for a dynamic HF management signal include that it be appropriate, accurate with absolute rather than relative values, actionable, and algorithmic. When the intent of monitoring is for active management of HF (Table 2), the signal also needs the right kinetics to respond rapidly after an intervention, which may undershoot or overshoot the goal: to be "reassessable" for that vital early relook. The necessary signal characteristics may differ, however, for patients with lower risk of events, such as those who undergo implantable cardioverter-defibrillator (ICD) implantation without a history of either HFH or chronic loop diuretic agent therapy (Table 2). Their monitoring may be surveillance for an unexpected deviation from stability that signals the need for a clinical reassessment. The most stringent requirements for remote monitoring could be exemplified by patients whose episodes of decompensated congestion qualify for local "hospital at home" programs, of which there are currently >140 in the United States.[27]

THE SIGNALS. Weights and Symptoms. Weights and symptoms were sentinel signals chosen for the landmark telemonitoring trials, which often also included vital signs. Flexible diuretic agent regimens based on daily weights clearly avert some HFHs, particularly in patients who have regular habits and high compliance with daily weighing. However, weights are a noisy signal, with fluctuations due to caloric balance and bowel habits in addition to fluid status. As shown by Chaudhry et al,[28] the typical patient has a <2 pound increase before HFH. Weight changes have shown only 10% to 20% sensitivity for episodes of worsening HF.[14] The rarity of weight changes before HFH in pressure monitoring trials may also reflect the inclusion of weight monitoring as "usual" care in the control arm. Symptoms are often not recognized until shortly before admission, and even those patients who recalled symptom changes often delayed seeking care because they were unsure of their significance.[29]

Ambulatory Cardiac Pressures. *Pivotal trials.* In the randomized blinded COMPASS (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure) trial reported by Bourge et al,[30] an implanted right ventricular pressure monitor was used to estimate PA diastolic pressures (PAD), leading to a 21% reduction in HF events, which was not significant when class IV patients were

included, some of whom had frequent outpatient intravenous inotropic infusions as events (Table 1). In addition, the benefit of monitoring depends on preserved responsiveness to changes in therapies. Intervention was triggered by PA pressure "peaks" without addressing high filling pressures at baseline. This experience allowed demonstration of the progressively higher risk of later HFH from plateau PAD levels >18 mm Hg.[31] In subsequent trials, the hemodynamic strategy was refined to address early reduction of elevated baseline pressures as well as later pressure elevations, even without clinical evidence of congestion. The randomized blinded CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) trial aimed to achieve and maintain plateau PAD below 22 mm Hg. As reported by Abraham et al,[32] this trial showed a 39% decrease in HFH. In the randomized GUIDE-HF (Hemodynamic-GUIDEd management of Heart Failure) trial, the pre-COVID-19 analysis approved by the U.S. Food and Drug Administration (FDA) showed significant reductions of HFH that were comparable between HFrEF (n = 531, HR: 0.71) and HFpEF (n = 398, HR: 0.70).[33] Led by Lindenfeld, this trial led to expansion of FDA approval for the PA monitoring device from class III to include class II HF, with risk of congestion identified either by HFH in the previous year or by elevated natriuretic peptide levels within 30 days (eg, B-type natriuretic peptide ≥250 pg/mL).

Left atrial pressure monitoring has also been used to guide therapy. The randomized LAPTOP (Left Atrial Pressure Monitoring to Optimize Heart Failure Therapy) trial showed a decrease in HFH that paralleled results from the earlier CHAMPION trial.[34] Trial enrollment was discontinued because of complications of implantation across the atrial septum. However a patient-level meta-analysis combining 363 LAPTOP patients undergoing continued follow-up with 456 patients in the CHAMPION trial and 531 in GUIDE-HF was recently presented,[35] showing significant reduction in mortality with ambulatory monitoring compared with standard HFM at 2 years (HR: 0.75; *P* = 0.04). More recently, the V-LAP left atrial pressure monitors have been successfully deployed across the atrial septum in 24 patients, with continued correlation between left atrial pressures and pulmonary capillary wedge pressure at 3 months.[36]

Real-world use. In early postapproval use of the implantable PA pressure monitor, 2,000 Medicare patients showed average mean PA pressure reduction of 3 mm during 6 months and 60% fewer HFHs than

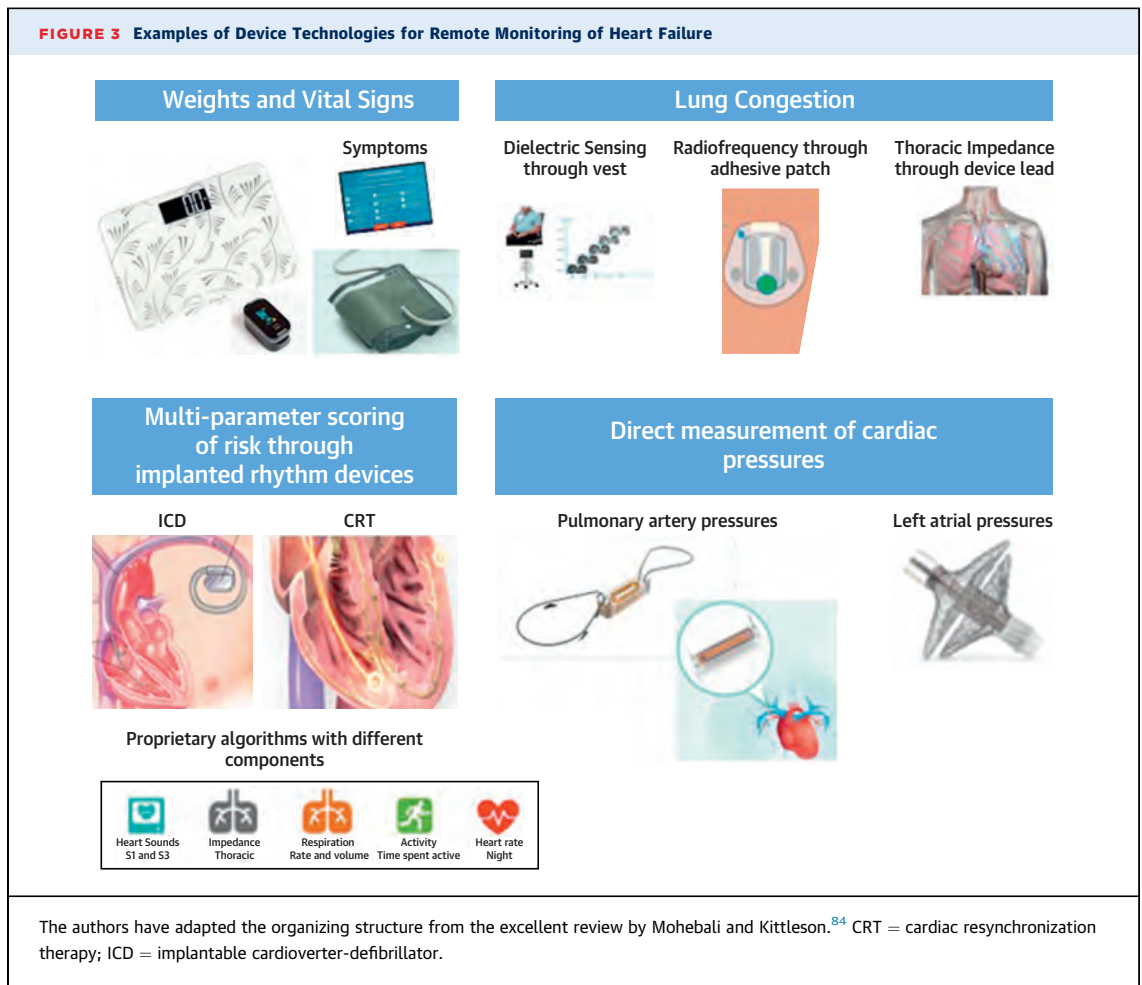**TABLE 2 Signal Specifications According to Intent of Monitoring**

Intent of Remote Monitoring	Routine Monitoring to Guide Ongoing Management of HF Therapies	Long-Term Surveillance to Alert for Deviation From Stability	Intensive Monitoring to Supervise Acute Decongestion in "Hospital at Home"
Target setting	Ambulatory HF requiring active titration of diuretic agents and other recommended Rx	Early-stage HF or HF improved EF	Acute HF congestion event qualifying for current HFH
Risk of HF event/year without remote monitoring	Moderate-high risk Often recent HF event or ongoing congestion (eg, high BNP/NT-proBNP) (eg, 20%-30% at 6 mo)	Predicted low risk without recent HFH or major elevation of BNP/NT-proBNP) (eg, 10% at 6 mo)	Acute risk of deterioration for transfer to hospital. HFH readmission range of 50% in next 6 months
Signal Characteristics	Routine Monitoring	Long-Term Surveillance	"Hospital at Home"
Relationship to physiology of decompensation	Signal linked tightly to cause and should indicate undertreatment or overtreatment in early relook	Signal with reliable correlation with worsening HF	Signal linked tightly to cause and should indicate undertreatment or overtreatment in real time.
Required specificity for HF as cause of change	High	Moderate	Very high
Kinetics of response to intervention	Rapid and reliable within 24-72 hours	May be delayed and incomplete	Rapid and reliable within 6-12 hours
Complexity and cost	Favorable if avoiding high risk of financial costs and easing inpatient bed shortage	Undesirable if low risk of HFH	Easily competitive with in-hospital care and monitoring
Scale of measurement	Absolute scale and continuous values to track trends closely and allow early relooks after intervention	Relative and time-averaged changes may be sufficient, May be "in or out" of alert zone, or at low-medium-high risk	Absolute scale and continuous values to track trends and responses to multiple interventions
Clinical Responses			
Response to alert	Therapy change within 24-72 hours, sooner if patient empowered	Arrange for clinical evaluation	24/7 ongoing adjustment of therapies
Anticipated action	Driven by signal value with other measures	Driven by clinical evaluation	Driven by signal value with other measures
Algorithm for therapy to relieve congestion	Initial stabilization may allow "graduation" to patient-centered algorithm for typical patterns	Driven by triggered clinical evaluation	Rx individualized using monitoring, video assessment, and on-site visits
Facilitated optimization of neurohormonal Rx	Tracks readiness and enhances tolerance and titration for neurohormonal therapies, combined with BP and HR information	Role of novel and combined parameters not yet established beyond HR and BP for tolerance	Tracks readiness after decongestion and enhances tolerance for early titration of neurohormonal therapies, combined with BP and HR monitoring
Frequency of intervention	Initially may be weekly or more often to reach stable target, often decrease to monthly or less when clinically stable	Rare until repeated exceptions warrant escalation to frequent guidance from signal responsive to changing therapies	At least twice daily during IV diuretic agents and transition to stable oral regimen, decreasing frequency during postdischarge period

BP = blood pressure; EF = ejection fraction; HF = heart failure; HFH = heart failure hospitalizations; HR = heart rate; IV = intravenous.

previously.[37] Similar results were seen in Europe[38] and the FDA-specified postapproval study of 1,200 patients. Reductions of PA pressures, HFH, and all-cause hospitalizations were sustained during the 2 years of follow-up.[21] Benefits have been comparable or greater for HFpEF, in the range of 50% reduction.[21,39] Obesity severely limits clinical assessment to follow congestion, but reductions in HFH during PA pressure monitoring have been comparable or greater in patients with obesity regardless of LVEF.[39] The results of ambulatory PA pressure monitoring have shown notable consistency across ejection fraction, sex, race, and academic or community HFM programs.

ASSESSMENTS OF EXTRAVASCULAR CONGESTION. Lung Water. Given that the most common symptom before HFH is dyspnea, measurement of lung congestion may present a highly relevant signal both as a marker to predict HFH and as a target to reduce dyspnea (Table 1, Figure 3). One way to assess pulmonary congestion is with thoracic impedance as a measure of lung water.[15] The majority of space occupied by lungs is filled with air, a poor electrical conductor. When transudative fluid, a good electrical conductor, occupies a higher proportion of lung volume, electrical impedance will decrease. This has been exploited to add additional monitoring capacity to modern implantable rhythm devices, most of which can monitor the electrical impedance between lead electrodes in the heart and the pulse generator on the chest wall, between which there is typically a portion of lung. Several small studies demonstrated a correlation between worsening HF and decreased thoracic impedance, 1 demonstrating an average 12% decrease in thoracic impedance occurring at an average of 18 days before HFH.[15] These led to

FIGURE 3   Examples of Device Technologies for Remote Monitoring of Heart Failure

The authors have adapted the organizing structure from the excellent review by Mohebali and Kittleson.[84] CRT = cardiac resynchronization therapy; ICD = implantable cardioverter-defibrillator.

multiple randomized controlled trials of the use of thoracic impedance to monitor HF (**Table 1**), which overall have not demonstrated benefit over usual management, with HR of 1.10 for HFH in an analysis of 2,494 subjects.[40] Recognized challenges include a substantial rate of alarms for which clinical evaluation did not reveal HF worsening. In 1 study the alerts were sent to the patients, who then sought attention, generating a higher number of clinic encounters without reducing HFH.[41] It is unclear to what extent the lack of demonstrated benefit reflects limitations of the thoracic impedance signal to detect rising or falling congestion, or the lack of consistent clinical responses to signal changes.

Thoracic impedance can also be used to measure changes in blood volume in the chest, and it has been applied to estimate stroke volume and cardiac output as well as filling pressures, referred to as impedance cardiography.[42] Partly on the basis of trends to predict events in outpatients, this technique was approved for use in hospitals and clinics.[43] However, subsequent correlations have been modest or poor

between impedance cardiography measures of cardiac output and PA pressure measurements, and neither correlated with outcomes in a substudy of the ESCAPE (Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness) sponsored by NHLBI.[44]

Lung water content has more recently been measured across the lung with a dielectric signal (**Table 1**, **Figure 3**). This focused electromagnetic signal is transmitted between 2 sensors embedded in a wearable chest garment, and the analyzed signal is used to calculate lung water content. Measurement of remote dielectric sensing (ReDS) has been validated against CT measurements of lung water, and in contrast to thoracic impedance, it provides an absolute value for lung water content; the normal average is 28%.[45] A threshold of 35% has been identified to predict HFH. The average lung water content measured at HFH admission was 40%, decreasing an absolute 18% by discharge.[46] In 1 study, use before discharge detected residual lung congestion in 32% of patients, and it guided an average 5.6 pounds of

further diuresis.[47] The technique was also used for management in the postdischarge HF clinic.[48] A randomized trial of 268 patients who were followed up for 6 months showed 48% HFH reduction in an analysis of patients who could be treated per protocol with the ReDS system in accordance with usage and defined algorithms.[49]

The impact of a novel radiofrequency-based wearable sensor to measure lung congestion has recently been tested in the Benefits of Microcor (μCor) in the Ambulatory Decompensated (BMAD) trial. Comparing 2 studies of this sensor patch applied to the lateral chest, management by the use of lung congestion measurements significantly reduced HFH compared with the study in which patch information was monitored but not used for intervention.[50]

Other Sites for Assessing Congestion. Other regions of extravascular congestion are also under investigation. The generation of speech can be affected by lung volumes, and its spectral parameters are influenced by swelling of soft tissues in the vocal tract. Digital speech technology tracked voice changes during decongestion in a study of 40 patients during HFH[51] and was shown recently in a community study to predict HFH with a sensitivity of 88%. Although assessment of peripheral edema in the feet is complicated by multiple dynamic factors, work is ongoing to identify changes in foot volume.[52]

MULTIPARAMETER SIGNALING FROM IMPLANTED DEVICES. Several investigators have leveraged the combination of multiple sensors that provide information from different aspects of HF physiology (Table 1). Combining the sensors into a risk index for surveillance should increase sensitivity to detect risk of HFH, but the multiple inputs can decrease the specificity of a positive signal, which then requires clinical evaluation to confirm a clinical change and select an intervention.

The first combination of multiple sensor signals from an ICD into a risk index included thoracic impedance, activity, and heart rate (night-time heart rate, rhythm, and heart rate variability) derived from several clinical trial databases of patients with ICDs. Combining these parameters, a HF risk score was derived and validated,[53] dividing subjects into those with low, medium, and high risk. The high-risk subjects constituted 10% of the population and had an event rate 10-fold higher than the lowest strata, which included 44% of subjects. This risk metric was incorporated weekly into HF management during the REM-HF (Remote Management of Heart Failure using Implantable Electronic Devices) trial,[54] but there was no impact on time to all-cause death or unplanned

cardiovascular hospitalization (HR: 1.01). A major limitation of this strategy may have been variability in the clinical response loops,[55] which in some cases relied on corroborating evidence from symptoms or weight trends before intervention.

The MultiSENSE (Multisensor Chronic Evaluation in Ambulatory Heart Failure Patients) risk index has been constructed from a trial prospectively designed to derive and validate the risk index using data collected from cardiac resynchronization therapy defibrillator (CRTD) devices. This information included not only thoracic impedance, heart rate, and activity but also heart sounds measured by an accelerometer, and respiratory rate and relative tidal volume measured by thoracic impedance. The MultiSENSE trial demonstrated a sensitivity of 70% and specificity of 85.7% for prediction of HF events. Furthermore, the time from alert to HF event was long: a median 34 days.[56] Importantly, the negative predictive value of not being in alert phase was 99.98%, and the proportion of patients in alert at any given time was only 16%. Furthermore, being in alert conferred a risk of 0.8 HF events per patient year, tenfold higher than the 0.08 events per patient year out of alert.[57]

A third multiparameter study reported findings from 918 subjects to develop and validate a risk index using data from CRTDs or ICDs including thoracic impedance, activity, and several heart rate parameters. The algorithm demonstrated a sensitivity of 66% and a false-positive rate of 0.76 alerts per patient-year, which could be decreased by adding clinical data.[58] The sensitivity and specificity of the algorithm is similar to the findings in MultiSENSE, but more data are needed to understand the performance of these indexes to predict events for patients in and out of the alert zone.

NEW WEARABLES. In the explosion of wearable technologies across the general population and in medical settings, many have not undergone FDA-level scrutiny, and few have undergone validation.[59] This creates a huge imbalance between consumer vs medical-grade technology,[60] and it raises concerns regarding the accuracy of wearables,[61] particularly when they are used to guide clinical care. Nonetheless, the promise of wearables is that they bring us closer to the data needed to detect change and act on it. Wearables further move health information and disease management into the hands of patients.[62]

It is crucial to understand what a wearable measures, how it reflects HF pathophysiology, and how it should drive algorithms. Simple measures such as step count have been associated with

TABLE 3 Examples of Digital Health Care Systems in Clinical Evaluation for Heart Failure
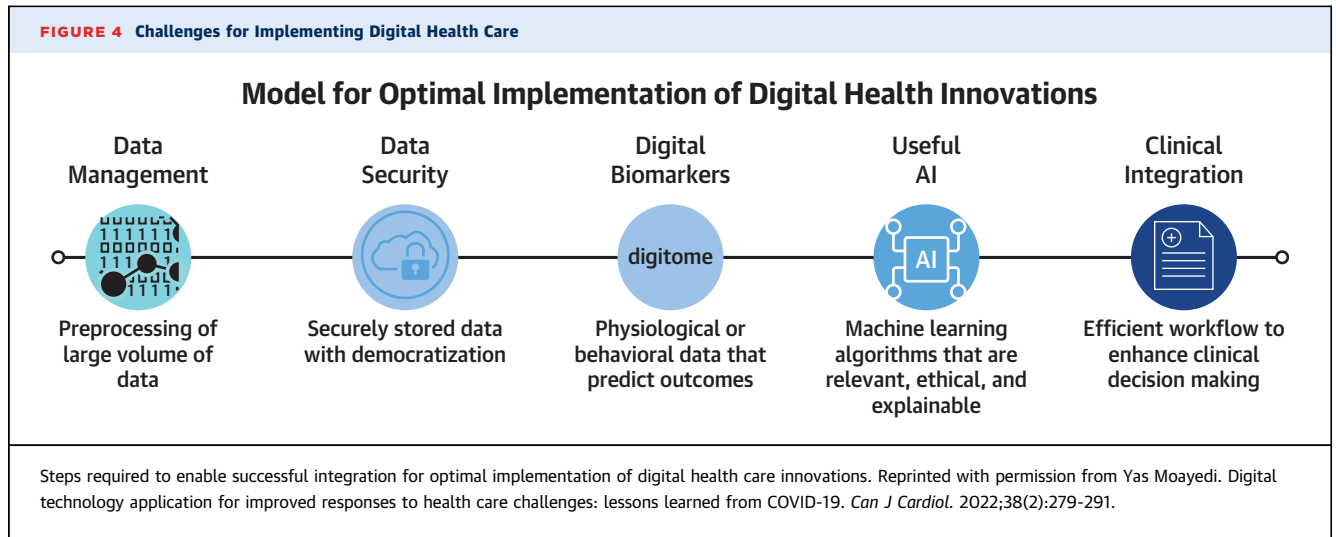
Name	Digital Health Care Intervention Name	Incorporated Signals	Description
Medly digital health care program	Medly	Weight, heart rate, blood pressure and symptoms	Extend use of in-app expert rules-based algorithm as in **Figure 5**, based on prior demonstration of 50% reduction in HFH in pragmatic trial of 315 pts[88] and shortened time to GDMT using predefined remote titration strategy in RCT of 108 participants.[89]
Sensor Controlled Digital Game for HF management (SCDG) NCT05056129	Sensor controlled digital game app	Weight monitoring, Physical activity and sensors using Withing's wearable monitors	Help the individual's avatar maintain good health and quality of life by using game points, earned via objective tracking of real time behaviors. Outcome is HFH within 6 months, number of days with sensor log for weight, BP, self-management (RCT 200 participants).
A Digital Solution for patients with HF NCT05193344	Sidekick Health platform	Participants enter data (on diet, exercise, weight, etc) and answer questionnaires	Digitally provide remote symptom monitoring and lifestyle intervention via a mobile platform. Outcomes are change in symptoms, KCCQ at 12 months (RCT 174 participants).
Evaluating the Efficacy of Digital Health Technology in the Treatment of CHF NCT04394754	BodyPort	A data-driven smart scale with proprietary sensor	Scale with proprietary sensor technology and AI algorithm provides enhanced cardiac monitoring and processing to determine fluid status noninvasively and assess risk. Outcomes QOL using KCCQ, HF admissions, GDMT, ED visits, mortality, device usage (RCT 182 participants).
Virtual Care to Improve Heart Failure Outcomes (VITAL-HF) NCT05602454	Story Health platform	Vital signs – blood pressure cuff and scale	Virtual care delivery via specialized platform with data transmitted to the treating clinician, who will create care plans for medication titration and make clinical decisions. Care plans implemented with assistance from health coaches Outcome GDMT(RCT 180 participants).
Artificial Intelligence Mobile Health Trial of A Digital Platform To Optimize Guideline Directed Heart Failure Therapy Using Wearable Sensors NCT04191330	BiovitalsHF	Continuous physiology data from remote vital sign monitoring devices AI mobile health platform	Cloud-based platform to manage initiation and titration of GDMT outside of normal or traditional clinical encounters Randomized parallel assignment 228 participants.

www.clinicaltrials.gov; accessed February 11, 2023.

AI = artificial intelligence; ED = emergency department; GDMT = guideline-directed medical therapy; HF = heart failure; HFH = heart failure hospitalizations; KCCQ = Kansas City Cardiomyopathy Questionnaire; QOL = quality of life; RCT = randomized controlled trial.

cardiopulmonary performance and functional class.[63] Omar et al[64] found that patients with lower daily physical activity had blunted cardiac index responses to a greater extent than elevated filling pressures during semisupine exercise. Many wearables and apps are being investigated alone or combined with self-care behavior modification (**Table 3**).

New technologies are proliferating, such as fiber-based technology to enable continuous monitoring.[65] The vest to measure lung fluid has already been investigated clinically, as discussed earlier. Edema may soon be measurable in real time by the use of wearable "smart" clothing made of edema textiles, for example "smart socks."[66] Small wearable ultrasound patches to monitor the function of the heart and other organs are now feasible for imaging and could potentially be applied for monitoring cardiac function and hemodynamics at home.[67] We are evolving toward electronic medicine with nanotech, nanosensors, electrochemical wearables, and smart textiles. One such potential innovation is "smart dust"—submillimeter-scale electronic devices that are remotely powered and provide electrical, optical, and/or chemical measurements.[68]

ARTIFICIAL INTELLIGENCE FOR COMPLEX PATTERNS OF SIGNALS AND RESPONSES. Between advanced electronic health records, clinical data including imaging, and the vast amount of data from patient wearables, the volume and complexity of information exceeds the capacity of the human mind to process. AI, including machine learning and deep learning, is often ideally suited for these large multivariate data sets of interactions.[69] The opportunities for continual learning and refinement of both signal and clinical response data should support the rapid evolution of algorithms for therapy, so-called adaptive AI. Principles of responsible AI[70] dictate rigorous evaluation, responsible deployment, and thoughtful reporting within ethical and regulatory standards.[71] We must prioritize inclusive health care AI while addressing biases.[72] There is little doubt that multiple levels of AI will be incorporated into the discovery and processing of remote monitoring signals for both automatic and clinician-facilitated HFM (**Figure 4**). To create manageable workflow for clinical teams, the acceleration of AI for automatic medical record documentation will need to keep pace with the increased traffic of signals and responses.

FIGURE 4 Challenges for Implementing Digital Health Care

Model for Optimal Implementation of Digital Health Innovations

Data Management	Data Security	Digital Biomarkers	Useful AI	Clinical Integration
Preprocessing of large volume of data	Securely stored data with democratization	Physiological or behavioral data that predict outcomes	Machine learning algorithms that are relevant, ethical, and explainable	Efficient workflow to enhance clinical decision making

Steps required to enable successful integration for optimal implementation of digital health care innovations. Reprinted with permission from Yas Moayedi. Digital technology application for improved responses to health care challenges: lessons learned from COVID-19. *Can J Cardiol.* 2022;38(2):279-291.

THE ALGORITHMS

When the TELE-HF (Telemonitoring to Improve Heart Failure Outcomes) trial failed to show benefit, a major concern was that responses to threshold crossings were not delineated to connect the signals with responses in the circle of management.[73] Similar criticism remains applicable to many current monitoring strategies. Algorithms need to incorporate the extent and speed with which signal thresholds are crossed, integrate other data, and then link to responses (Central Illustration), which will be refined by human and machine learning. There are currently more detailed analyses of PA pressure–guided interventions than for other remote monitoring.[74] Active protocols for the approved device require a reclining PAD target level specified per patient, with a default range of 8 to 22 mm Hg. Targets are being established for sitting PA mean pressures in the PA monitoring device in the PROACTIVE-HF (Prospective Trial Evaluating the Cordella Pulmonary Artery Sensor in Heart Failure),[75] in which transmission also includes parallel trending of weight, vital signs, and symptoms. Algorithms generally direct initial responses to increase or decrease diuretic agent dosing with subsequent consideration of changes in neurohormonal antagonists, nitrates, or other vasodilators. Diuretic agents accounted for 62% of changes during the first 6 months in the CHAMPION trial of PA monitoring, with 25% in neurohormonal antagonists and 11% in direct vasodilators.[74] In patients treated for 12 months with alerts from the HeartLogic device algorithm, 82% of changes were in diuretic agents and 18% in neurohormonal antagonists.[76] Contemporary algorithms to decrease PA pressures should

increasingly incorporate therapies beyond diuretic agents, such as nitrates, which are well known to decrease filling pressures, also sacubitril/valsartan and empagliflozin which have been shown to reduce elevated PA pressures during ambulatory PA monitoring.[77,78]

CONNECTING THE CIRCLES BETWEEN CLINICS AND HOME

TRADITIONAL OFFICE-BASED CARE. The traditional model of HF management has been based on "episodes of care," with scheduled office visits and urgent hospitalizations followed by more frequent office visits. Remote patient monitoring at home was originally designed to complement these visits, but contemporary trends indicate that remote management will come to dominate the pattern of care.

Although it was initially hoped that telemonitoring would reduce the work load for traditional HF clinics, the early trials did not improve outcomes but nonetheless delivered high data volume requiring personal staff attention. In the Tele-HF trial, the average patient generated 35 variances requiring staff-patient contact in a 6-month period.[4] This added load was similar to that generated in the BEAT-HF (Better Effectiveness After Transition-Heart Failure) trial,[6] in which transmissions exceeding thresholds generated an average of 22 triggered contacts with each patient in addition to their 6 scheduled calls during 6 months. Without specified algorithms, most interventions for these trials required triangulation between staff receiving transmissions and the prescribing clinicians, further increasing work load and lengthening the loop before reconnecting with the patient (Central Illustration).

The best outcomes in a traditional telemonitoring trial were shown by Koehler et al[79] in the TIM-HF2 (Telemedical Interventional Management in Heart Failure II) trial, with decrease in days hospitalized or dead from 11.34 to 7.86 per 100 patient-years. A unique component of the TIM-HF network was sponsorship of an emergency call center staffed 24/7 by physicians who could access home monitoring data and respond immediately to the patient.[80] Of 326 calls made to the urgent center by the 1,119 monitored patients, most occurred outside working hours, but only 53% led to hospitalization, compared with 84% for calls made to the usual public emergency service. This remarkable resource of on-call physician staff was likely important to the reduction of hospitalizations seen in TIM-HF2. This experience highlights the value of immediate connection linked to HFM staff around the clock, which is rarely supported in clinical HF settings but is common after heart transplantation or implantation of an LVAD.

SHIFTING TOWARD HOME DURING COVID-19. During COVID-19, there was a major shift in HFM away from the hospital/clinic settings toward treating patients at home. Emergency department visits and hospitalizations decreased by up to 50% for patients with HF.[81,82] The decrease was attributed in part to aversion to hospital exposure but also likely reflected better medical adherence, limited social eating, and fewer endemic infections. The physiological impact of quarantine on HF was illuminated in the GUIDE-HF study of PA pressure-guided therapy.[20] During lockdown, PA pressures for both control and monitored arms converged to lower baselines and required 50% fewer interventions than during the primary study period. Recovering from COVID-19, patients also became comfortable with self-monitoring of oxygen saturation at home.
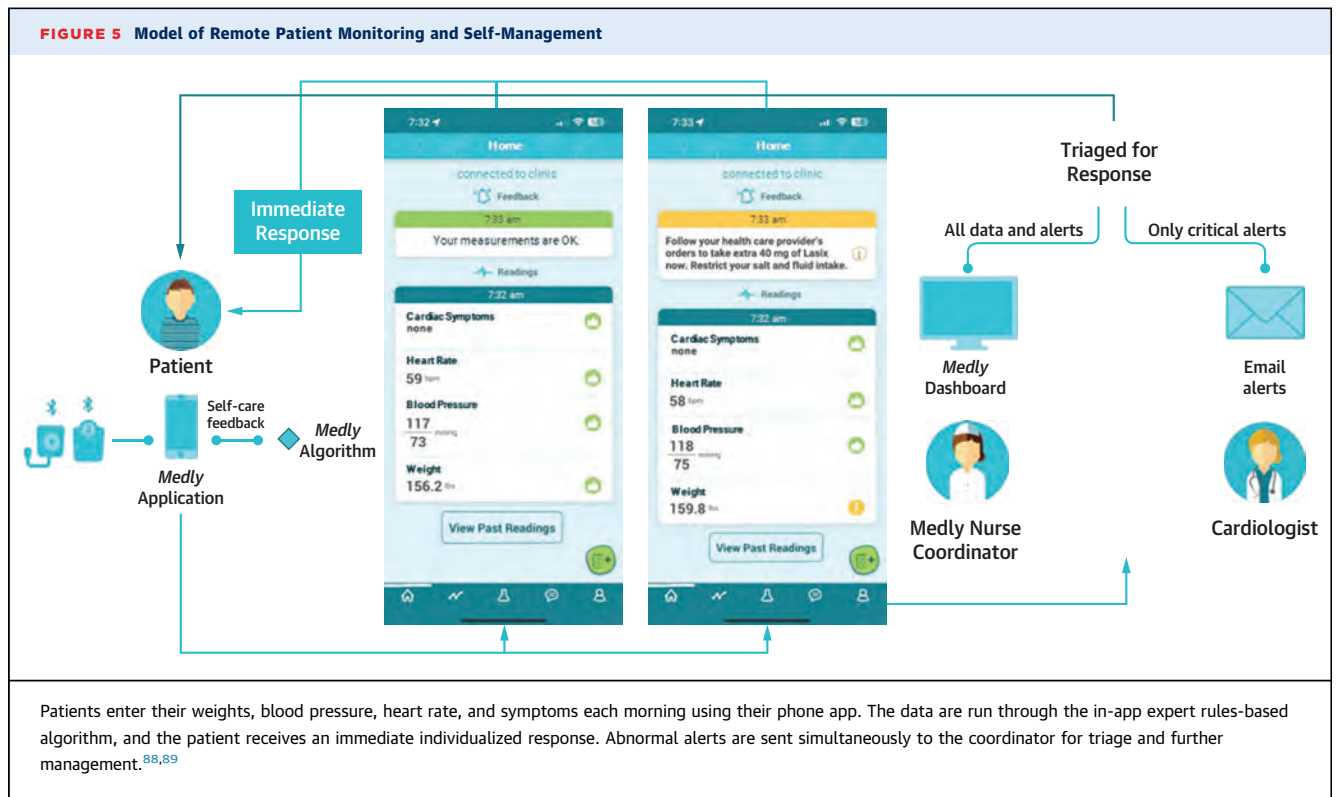
Although COVID-19 was a "black swan" that disrupted many aspects of global society,[83] one silver wing for health care has been the accelerated acceptance within a few weeks of telehealth technology that might otherwise have taken many years.[84] Telehealth visits increased rapidly: up to 30% of all ambulatory visits in the United States.[85] Compared with in-person visits, telehealth visits appeared efficient to provide care safely at a distance, with no signal for increased mortality or hospitalization.[86] Xu et al[87] found that the risk for 30-day or 90-day readmission was decreased by almost 50% by either telemedicine or in-person follow-up visit compared with no follow-up care. The visual contact was vital, however, because follow-up care by telephone alone was associated with higher rates of Emergency department visits (HR: 1.34) and death (HR: 1.82).[86]

There has been concern, however, that unstructured telehealth care during the COVID-19 era has not provided enough engagement to titrate HF therapies recommended to decrease disease progression. In a cross-sectional study of 176,781 ambulatory cardiology visits comparing the previous era with the COVID-19 era, there was a stepwise reduction in the prescriptions ordered: from two-thirds of visits before COVID-19 to the COVID-19 period, during which prescriptions were ordered in one-half of in-person visits, one-third of video visits, and one-fourth of telephone visits.[86]

The reduction of in-person assessments during COVID-19 has increased appreciation of the relevance of remote monitoring and the need for broader platforms to integrate telehealth and monitoring within HFM programs.[84] One example of a promising platform for protocolized HF management leveraged during the COVID-19 experience in Canada is the Medly program, which combines an in-app expert rules program based on home measurements (weight, heart rate, blood pressure, and symptoms) combined with an integrated nurse-led model of care, with 1 nurse or nurse practitioner able to manage the care of up to 300 patients (**Figure 5**). In a pragmatic study of 315 patients, Medly improved self-care and quality of life while reducing HFH and all-cause hospitalizations by 50% and 24%, respectively.[88] In a subsequent randomized trial of 108 patients, Medly reduced in-person clinic visits by 40% while achieving guideline-recommended therapy 60 days sooner than usual care.[89] Now part of the Ontario quality-based program for HF, Medly is currently deployed at multiple sites in the region.

As another result of COVID-19, decompensation previously treated in the hospital may more frequently be managed at home. Although "hospital at home" was described in 2005 as decreasing both costs and delirium in Medicare patients in Baltimore,[90] most experience has been in other countries.[91] However, there is now rapid expansion of "hospital at home" in the United States,[27] following the Centers for Medicare and Medicaid Services (CMS) Acute Hospital Care at Home Waiver in 2020, authorizing comparable reimbursement for home management of acute on chronic HF as for in-hospital care. Assuming that the CMS waiver and commercial payors continue to finance the necessary staffing ratio, this could represent a laboratory to enhance the efficacy and safety of decongestion, using remote monitors with appropriately reliable and responsive signals (**Table 2**).

PATIENT EMPOWERMENT IN THE CENTER. The minimum engagement necessary from the patient is

FIGURE 5 Model of Remote Patient Monitoring and Self-Management

Patients enter their weights, blood pressure, heart rate, and symptoms each morning using their phone app. The data are run through the in-app expert rules-based algorithm, and the patient receives an immediate individualized response. Abnormal alerts are sent simultaneously to the coordinator for triage and further management.[88,89]

to transmit and receive information and to adhere to instructions for changing medications and transmitting for early relooks. The potential impact can be greatly magnified, however, if patients can contribute and receive information in a real-time context that encourages understanding of their HF and modification of health behaviors. Feedback provided by the monitoring team to patients about their physiological data can help patients to associate behavior with HF signals (**Figure 2**). A "pseudo-placebo" effect was described in 1 study in which initiation of ambulatory hemodynamic monitoring improved patient adherence with medications, exercise, and dietary recommendations.[92] Physiological feedback will change behavior more powerfully when patients access it directly and can see the results of their actions and changes in therapy.

In the United States, 1 in 5 people currently use some type of handheld phone application measuring physical parameters such as heart rate or stepcount.[93] Monitoring and response to glucose levels is now standard self-management for patients with diabetes. With previous ambulatory left atrial pressure monitoring, feasibility and early effectiveness was demonstrated for an initial period of open access with clinicians to define patient patterns to personalize a response algorithm, followed by patient "graduation"

to direct handheld access to their signals and algorithmic-driven dosing of diuretic agent.[34] The integrated Medly program supported in Canada provides personalized instructions for diuretic agents directed back to the patient[89] (**Figure 5**). Direct patient access to data trends and personal daily algorithms will be used in arms of the ongoing and subsequent PROACTIVE trials, integrating sitting PA mean pressures with weights, vital signs, and symptoms.[75] Ongoing clinical investigation of the newer left atrial pressure monitor also includes patient instructions through a handheld app. These tight loops for HF monitoring can minimize response times and engage and empower patients while decreasing dependence and burden on the clinical team (**Central Illustration**). Patients have long been able to access their weights, heart rate, and blood pressures, but regulatory approval for access to more complex physiological signals awaits confirmation that patient empowerment will not lead to adverse events such as volume depletion.

DIGITAL HEALTH CARE WITH HEART FAILURE

The integration of remote monitoring with the circles of HFM will include multiple components of digital health care, the broad scope of which has been

defined by the FDA to encompass mobile health (using mobile devices), telehealth and telemedicine, health information technology, and specific applications of personalized medicine.[94] The FDA has established a Digital Health Center of Excellence to "innovate, connect, and share in order to empower." Multiple issues crucial to the implementation of digital health care have been reviewed by the American College of Cardiology Task Force[95] and by Brahmbhatt et al[96] in Canada.

FLEXIBLE PLATFORMS FOR SIGNALS AND RESPONSES. Patients who benefit from integrated HFM with remote monitoring will include not only the typical HFrEF and HFpEF populations but also patients with other specific diagnoses that place them at high risk for recurrent congestion. Examples include congenital heart disease, pulmonary hypertension, hypertrophic cardiomyopathy, recent valve procedures or atrial fibrillation ablation, and chronic renal failure. To realize the full potential of digital health care for HF management,[95] it is key to ascertain which signals and connections best match each patient according to the intent for surveillance vs management, the type of monitor, and the care settings. Situational awareness, capacity building, and cultural safety are essential to extend digital health care to underserved populations.[97] Given patient complexity and the long trajectory of HF, there will be no one-size-fits-all approach. Basic platforms need to accommodate different sensors and to be integrated into the local electronic medical records. A recent advance in digital integration has been direct transfer of PA pressure data and triggered interventions into the EPIC electronic medical record system to support documentation and also reimbursement for outpatient monitoring, as exemplified for a system of 7 hospitals in Hartford HealthCare (personal oral and email communication, Dr. Jason Gluck, Hartford, Connecticut, February 13, 2023).

FUTURE VALIDATION OF REMOTE MONITORING STRATEGIES. Pragmatic Trial Design. The history of remote monitoring for HF has been remarkably balanced between the substantial weight of repeated experiences demonstrating lack of benefit for some strategies, and the similar weight of repeated experiences confirming benefit for others. Looking forward, however, the traditional randomized trial format for testing integrated digital HFM will likely be outpaced by the expanding variety of platforms and the accelerating clinical demand. The maturation of physiological insights and team structures could contaminate traditional care of "control" patients within trial centers, whereas site randomization involves multiple unmatched factors. Neither is it feasible any longer to blind patients to whether their signals guide therapy, now that the central role of patients' engagement to change their course of disease has been recognized. Furthermore, rapid updates enabled by machine learning to revise detection and response algorithms will create dynamic platforms that improve throughout a trial. Pragmatic design will be crucial for future HFM trials.

Counting Outcomes Beyond HFH. HFH have served as the favored coins of the realm to prove the efficacy of HF therapies, in part because they represent the largest HF expenditure. However, other high costs are physical and emotional limitations to patient activities, quality of life, and patient sense of control over HF.[98] Even without HFH, congestion is associated with poorer quality of life.[99] Resolution of even 1 clinical component of congestion was associated with a 5-point improvement in quality of life in the pivotal trial of sacubitril/valsartan.[100] PA pressure-guided management has been associated with improved quality of life[32] and improved patient illness perception, including increased sense of control and reduced concern about HF over time.[92,101,102] Future studies should carefully assess the impacts of HFM on life satisfaction and disease impact for patients and their caregivers.

In addition to detecting trends of worsening, home monitoring should facilitate personalization of therapies recommended to decrease HF progression. For patients with improved ejection fraction, monitoring may also facilitate down-titration of diuretic agents. Along the disease trajectory, reduction in PA pressures during 6 months of guided therapy predicts better survival,[103] in part through protecting right heart function, with likely reduction of the cardiorenal syndrome and congestive hepatopathy. When HF worsens despite recommended therapies and monitoring, monitored recognition of instability may trigger timely referral for heart transplantation or implantation of an LVAD.

Monitoring the Disease or the Patient? As the data and diagnoses increase, validation of signals will become increasingly complex. In seeking a signal to herald a specific event, we will be disappointed by false-positive alerts. However, many of these alerts may instead be true positives for the patient, bringing attention to other conditions that warrant diagnosis and therapy. Chronic pulmonary disease, kidney disease, and diabetes are each present in more than one-third of patients with HF. Aspirational

FIGURE 6 The Digital Divide
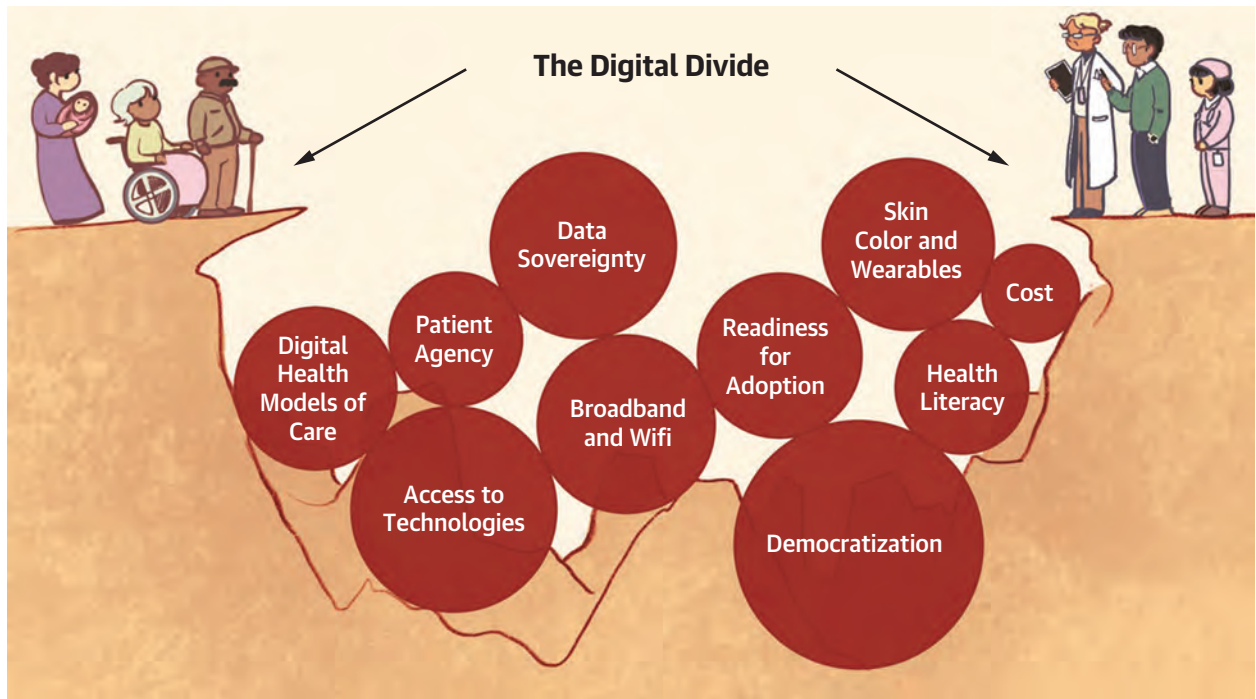
Examples of challenges that need to be bridged to enable equitable access to care through digital health care platforms.

development of remote monitoring platforms could include an even broader team to manage the multiple other diagnoses that travel with HF.

ADVANCING EQUITY OF ACCESS FOR PATIENTS WITH HF

The rates of HF hospitalization are about 50% higher in the Black population and in zip codes representing the lowest income quartile, particularly in those aged between 18 and 45 years.[104] Social determinants of health are increasingly recognized as responsible for up to 80% of health outcomes. The pandemic illuminated but did not create the deeply rooted inequities in health care access and outcomes in vulnerable populations, such as those with sociodemographic risk factors.[105] The quadruple aims of improving population health, enhancing the patient experience, decreasing costs, and strengthening support structures for clinicians have now been encircled by the fifth aim of improving equity of health care.[106]

THE DIGITAL DIVIDE. Digital health literacy must be part of the assessment and implementation of digital health care, with appropriate modification of the

environment. Multiple obstacles will need to be addressed to bridge the digital divide between patients and digital health care programs (**Figure 6**). The urgent push to virtual care highlighted disparities in access to high-speed reliable internet needed for video visits, recognized as another key social determinant of health.[107] Increasing availability of broadband will increase access to remote management, treating patients where they are with reduced need to travel for health care.[108] Connecting the loop will also involve caregivers and in some cases community coaches or other patients to act as set-up assistants and as health care "buddies."[109] Tailoring digital health care tools to local context, focusing on a user-centered design, can improve outcomes. For example, in a pilot study of 72 patients in Uganda, the Medly program was integrated within a government mobile health platform using an Unstructured Supplementary Service Data text-based alert monitoring program that significantly reduced HFH.[110]

EQUALIZING ACCESS TO THE CARE TEAMS. Assembling reliable and effective platforms will be vital to help patients maintain connections with care teams, but the existence of these platforms will in no way

ensure accessibility to HF care teams, particularly in areas of deprivation. During hospitalization[111] and after discharge,[112] access to cardiologist care is consistently lower for patients defined by minority race and additionally by zip codes with higher deprivation indices—a disparity seen also in the single-payer system in Canada.[113]

A model interdisciplinary program designed to provide access and improve outcomes for underserved populations with HF has been created at Grady Hospital in Atlanta.[114] Routine screening of social determinants of health through the electronic health record triggers key services to include a pharmacist, a social worker, and a community health worker, combined with direct HFM dominated by advanced-practice practitioners. Such truly multidisciplinary programs will be vital to derive the optimal benefit as digital health care platforms enter neighborhoods with high deprivation indices.

UNIVERSAL GAPS IN ACCESS TO HF MANAGEMENT.

The multidisciplinary model exemplified by the Grady HF program in Atlanta aligns closely with the level I recommendation for all HF programs "to facilitate the implementation of GDMT, address potential barriers to self-care, reduce the risk of subsequent HFH, and improve survival."[115] This aspirational recommendation is hard to enact for many of the estimated 6.7 million patients with HF in the United States, where there were only 1,400 certified HF physicians as of 2022, and many HF fellowship positions went unfilled. To approach this ideal of care across populations, focused curricula of HF and approved digital health care technology could be condensed for practical application by advanced-practice providers, such as those in the Grady program, who could then also facilitate recommended HFM in primary cardiology practices. Across the varied settings, HFM will require enhanced infrastructure of collaboration with community health care professionals (**Central Illustration**) and expedited triage to heart failure specialists as available.

SUMMARY

Early telemonitoring trials were disappointing but guided us to develop more effective remote monitoring. To manage HF at home, signals need to be accurate and actionable, with response kinetics for early relooks after intervention. The major target for decreasing HFH and improving quality of life is relief and prevention of congestion, for which tracking of cardiac filling pressures or lung water content has shown most benefit thus far. Algorithms need to

be personalized with more precision for signal thresholds and for levels of intervention, some of which should be automated for direct patient access. For patients at lower risk of HF events, multiparameter scores from implanted rhythm devices have identified patient trends for which clinical evaluation may be warranted. The COVID-19 epidemic accelerated transition to remote care away from clinics, preparing for new digital health care platforms to accommodate multiple technologies and empower patients. Addressing inequities will require bridging the digital divide and planning to fill the universally deep gap in staff providing HFM.

INTO THE FUTURE

Given Moore's law and the uncharted acceleration of AI, we will continue to see technological innovation move through the dawn of digital medicine into a projected 3-trillion-dollar industry.[116] Digital health care is sometimes proposed to decrease the need for human providers of health care. On the contrary, the need has never been greater to address the crisis of trust in health care. The development of digital health care technologies will not replace the multidisciplinary teams vital to equitable access in the expanding HF populations. However, as predicted by Mesko, "Automation won't replace physicians, but those using automation will replace those who don't."[117] If we can elevate priority for universal access to HFM care teams and remote management, we can share in deep learning about the physiological patterns of ambulatory HF and strive to renew Peabody's art[118] of caring for the patient.

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