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Cardiology

A Member Publication of the American College of Cardiology

GLOBAL TRENDS IN CVD BURDEN

Understanding the Scope to Devise Solutions

January 2021 Vol. 50 No. 1

UpFront

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Have your amyloidosis research featured in an upcoming special issue of *JACC: CardioOncology*. The deadline for submissions is April 15 to submit your papers for a special focus issue on amyloidosis being published in *JACC: CardioOncology*.

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The American College of Cardiology envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the Mission of the College and its more than 54,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned *JACC* Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit *ACC.org*.

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Peter C. Block, MD, FACC
Editor-in-Chief

TAVR For One! But TAVR For All?

Interventional cardiology is now more than 15 years into the use of TAVR, ever since **G. Alain Cribier, MD,** performed the first case in April 2002. The devices are now pretty slick, and so-called second- and third-generation devices have appeared. Paravalvular leaks are now less of an issue. Some enthusiasts are simply saying that TAVR is now "for all."

The appeal of TAVR is clear. The procedure is quick, hospitalizations in straightforward cases are short, general anesthesia is not necessary, use of hospital resources is less, patients are up and about feeling better in less time, and so forth. As a result, the use of TAVR is expanding to lower (and lower) risk and younger (and younger) patients.

Is it time to hit the "pause" button and reflect?

In surveying the TAVR landscape, there are important issues still to be answered. Here are a few of them.

What did the randomized TAVR trials really tell us? PARTNER IB and the CoreValve Extreme Risk trials are no-brainers. TAVR was a clear winner over paired patients having medical therapy. But after those first trials, it gets a bit more complicated.

For patients at high risk (PARTNER IA, CoreValve High Risk) and intermediate risk (PARTNER 2A, PARTNER 2 S3i, SURTAVI) outcomes showed that TAVR and SAVR had equal outcomes.

In low-risk patients (PARTNER 3, CoreValve EVOLUT R), TAVR was noninferior to SAVR for the primary outcome of death, stroke and repeat hospitalization; in fact, TAVR showed superiority on additional analysis. What drove the differences? Mostly repeat hospitalizations in both trials. Death between SAVR and TAVR was not statistically significant in both trials, which was perhaps expected given the low risk of the patients. Stroke was low (at roughly <3% for both SAVR and TAVR) but just favored TAVR statistically (embolic protection devices were not allowed in the trials).

Is it time to hit the "pause" button and reflect? In surveying the TAVR landscape, there are important issues still to be answered.

The PARTNER 3 trial, based on these findings, concluded that TAVR through one year *should be* considered preferred therapy in low-risk patients, while the EVOLUT R conclusions were slightly more conservative: TAVR *may be* preferred strategy to surgery in low-risk patients. Importantly, 10-year follow-up is planned for both trials.

So, can we really conclude that TAVR is for all? Not so fast!

Before sending that 50-year old patient with aortic stenosis to the cath lab for her/his TAVR, consider these questions.

What age groups were actually studied in these trials? The mean age was approximately 73 years in both! Can these data be applied to patients 20 years or so younger? In PARTNER 3, only 7% of patients were <65 years. In EVOLUTE R only 6% were <65 years and 1.3% were <60 years.

What about pacemaker need? At one month, the Evolute R trial reported approximately 17% vs. 6% pacemaker use for TAVR and SAVR respectively. PARTNER 3 reported 6.5% vs. 4%, respectively. Meddling with the conduction system just below the aortic annulus has its price, but surgery still has the edge.

What about coexisting coronary disease? The exclusion criterion for extensive coronary disease in PARTNER 3 was a Syntax Score >32, and in EvolutR >22. Simply saying that higher degrees of coronary disease can be treated with concomitant/additional stenting has to be called into question – especially now that we have longer term follow-up of the Syntax trials that show better surgical bypass results in complex disease.

Where do we stand on the pesky bicuspid valve question? Most younger patients with aortic stenosis have bicuspid valves. Data are sparse and no randomized trials of TAVR vs. SAVR have been done. The self-expanding CoreValve was studied in such patients and the results presented at ACC.20/WCC. The overall number was small (the study prospectively tracked 150 patients). On average, patients were 70 years old and had a Society of Thoracic Surgeons risk score of 1.4%. At 30 days, 1.3% of patients had died or experienced a disabling stroke. Of patients with a Sievers type 0 valve, roughly 15% had mild paravalvular leak after the procedure. That amount of leak in a 50-year-old might not be a good thing over the next 30 years. Also, remember that many patients with congenital bicuspid valves also have associated proximal aortopathy. Interventionalists are eyeing that target for transcatheter therapy, but for now that is surgical territory.

What about valve size? If the annulus is too large or too small, a perfect transcatheter valve fit may be difficult. For small annular sizes, patient/prosthesis mismatch is a real issue. Especially for younger patients the hemodynamics of persistent outflow tract obstruction are long term issues. SAVR surgeons are not immune to producing patient/prosthesis mismatch. In the CoreValve High Risk trial, severe patient/prosthesis mismatch occurred in approximately 21% of patients. But, if needed and possible, SAVR surgeons can enlarge the aortic annulus and outflow; TAVR cannot.

A frank patient-physician discussion, or better a patient-heart team discussion **is still an important part of the equation for all involved** to outline the risk-benefit ratio of TAVR vs. SAVR for many.

Bioprosthetic valves will, sooner or later, deteriorate. TAVR-in-TAVR can be performed, but at what risk? Data from the TRANSIT trial presented at TCT Connect 2020 indicate that in 172 patients from multiple international centers, the mortality at one year was 10%, with a cardiovascular mortality of about 6%. Many such patients have few other options, but surgery can be performed in some. Perhaps the option of a mechanical prosthesis originally placed would have been a better option in young patients despite the long-term anticoagulation issue.

Finally, there are absolute contraindications to TAVR: endocarditis, pure aortic regurgitation in a valve that might be surgically reparable, severe left ventricular outflow tract calcification, surgical "other valve" considerations, etc.

TAVR is a great alternative to SAVR in lots of patients – especially the elderly and those with morbidities that directly affect surgical risk. However, there are still many unanswered issues about which we have limited data. Should we accept that TAVR is for all? Not yet! For many patients facing aortic valve replacement, it is still imperative that we confront what we know and what we do not know. A frank patient-physician discussion, or better a patient-heart team discussion is still an important part of the equation for all involved to outline the risk-benefit ratio of TAVR vs. SAVR for many.

Editor's Note: Turn to page 14 for a feature on TAVR and page 34 to learn about the new ACC/AHA Guideline on Valvular Heart Disease.

Peter C. Block, MD, FACC, is a professor of medicine and cardiology at Emory University Hospital and School of Medicine in Atlanta, GA. He thanks **Michael J. Reardon, MD, FACC,** for a summary of many of these data.

ACC Joining Forces With BioIntelliSense Around Remote Cardiac Care

The ACC and BioIntelliSense, Inc., a continuous health monitoring and clinical intelligence company, have formed a strategic collaboration that combines innovative medical-grade wearable devices and data science to advance remote patient monitoring programs for cardiac care. The ACC will also offer the BioButton COVID-19 Screening Solution to provide an added layer of safety at ACC.21 in Atlanta in May.

The FDA-cleared BioSticker and medical-grade BioButton wearable devices allow for continuous vital sign monitoring of temperature, heart rate and respiratory rate at rest to enable early detection of adverse vital sign trends through its proprietary biosensor technology and advanced analytics. The strategic collaboration will combine ACC's clinical expertise in heart health with BioIntelliSense's effortless user experience and multi-parameter monitoring to make remote cardiac care scalable, reliable and cost effective.

"The ACC – and the cardiovascular community as a whole – has a long history of advancing innovative solutions to transform cardiovascular care and patient outcomes," says ACC President **Athena Poppas, MD**, FACC. "We are excited by the opportunity to partner with BioIntelliSense and be on the cutting edge of an innovative technology with real-time health data and feedback."

> "We are proud to form a strategic collaboration with the American College of Cardiology to **advance virtual care and remote patient monitoring (RPM) programs that can transform cardiac care.**"
>
> **James Mault, MD**

Look for the BioButton at ACC.21 as part of ongoing efforts to create a healthy and safe environment for attendees, exhibitors and staff in line with all current directives and recommendations. In addition to all CDC recommended COVID-19 safety protocols, ACC.21 conference attendees will have the option to participate in the BioButton COVID-19 Screening Solution for continuous vital sign and symptom monitoring for COVID-like infection. ACC.21 is the first major medical conference to use the BioButton solution.

"We are proud to form a strategic collaboration with the American College of Cardiology to advance virtual care and remote patient monitoring (RPM) programs that can transform cardiac care," says BioIntelliSense CEO **James Mault, MD**. "Together with the ACC, we can provide the cardiology community with medical-grade monitoring devices, clinically validated algorithms and RPM education that will have a profound impact on routine patient care globally. The inclusion of BioButton COVID-19 Screening Program to the safety measures for the ACC Scientific Session will also serve to provide [attendees] an opportunity to experience the simplicity of virtual care and effortless remote monitoring."

Look for the BioButton at ACC.21 as part of ongoing efforts to create a healthy and safe environment for attendees, exhibitors and staff in line with all current directives and recommendations.

ACC Names Jian'an Wang Inaugural Editor-in-Chief of *JACC: Asia*

Jian'an Wang, MD, PhD, FACC, has been named the inaugural editor-of-chief of *JACC: Asia*, the ACC's first region-specific, open access cardiovascular journal with original peer-reviewed content. The Journal will publish original manuscripts and clinical practice guidelines specific to East Asian populations and by Asian authors.

Wang is a physician scientist who serves as the chair of the Heart Center at the Second Affiliated Hospital at Zhejiang University School of Medicine in China. He is also a professor and associate dean at Zhejiang University School of Medicine.

A leading interventional cardiologist, Wang has spearheaded the efforts in establishing and developing one of the largest valvular heart disease programs in Asia and has also developed several innovative devices for valvular interventions, in collaboration with engineers, cardiovascular colleagues and manufacturers, that have been approved by the China Food and Drug Administration. His research work focuses on improving the efficacy of stem cell implantation in infarcted myocardium through hypoxemic preconditioning, which has been validated on rodent model, non-human primate model and phase-1 clinical studies.

"It is a great honor and privilege to serve as the first editor-in-chief of *JACC: Asia*," Wang says. "Our editorial team is excited to gather and publish the important scientific cardiovascular research coming from China, Japan and South Korea to help improve cardiovascular care and save lives. We look forward to working closely with cardiovascular research authors in the region and the *JACC* team to achieve these efforts."

The first issue of *JACC: Asia* will publish early this year, with a call for papers happening soon. Learn more at *JACC.org*.

> "Our editorial team is excited to gather and publish the **important scientific cardiovascular research coming from China, Japan and South Korea to help improve cardiovascular care and save lives.**"
>
> **Jian'an Wang, MD, PhD, FACC**

JACC Asia

New TRANSFORM: ACS Program Aims to Optimize ACS Care

The ACC, in collaboration with Amgen and Veradigm, have announced a new national study to transform care for acute coronary syndrome (ACS) patients at risk for future cardiovascular events. TRANSFORM: Accelerating Lipid Lowering Post ACS (TRANSFORM: ACS) will ensure ACS patients quickly receive cholesterol testing in the hospital and guideline-recommended therapies to reduce LDL-C in the hospital and upon discharge.

> **"ACC is mission driven to transform cardiovascular care for all patients**, and this novel approach should reduce the risk of recurrent major adverse events."
>
> **Athena Poppas, MD, FACC**

The primary goal of the TRANSFORM: ACS program will be to improve the rate of lipid-panel testing and lipid-lowering treatment intensification in ACS patients within 75 days after hospital discharge. Rapid cholesterol testing after a cardiovascular event within the hospital is hypothesized to drive initiation of lipid-lowering treatment within the first year post ACS, which could increase compliance and help patients avoid events more rapidly than current standard of care.

"Research has noted gaps in optimal care delivery for ACS patients. Our collaborative study will investigate mechanisms for early initiation, and test pilots for close follow-up, of lipid-lowering therapies," says ACC President **Athena Poppas, MD, FACC**. "ACC is mission driven to transform cardiovascular care for all patients, and this novel approach should reduce the risk of recurrent major adverse events."

The project will have two phases. Phase one will focus on supporting in-hospital lipid-lowering treatment of post-ACS patients as recommended, while phase two will evaluate quality improvement by following discharged ACS patients into the outpatient care setting to evaluate trends in treatment and risk prevention for up to a year post-discharge.

TRANSFORM: ACS will leverage the NCDR Cath PCI and Chest Pain – MI hospital registries, along with the Allscripts outpatient EHR and the PINNACLE Registry, operated by Veradigm in association with the ACC, to identify hospitals for intervention as well as affiliated outpatient clinics. Additionally, MedAxiom will develop a protocol with participating hospitals to certify clinician and health system engagement and retainment, ensuring goals of this program are met.

"LDL-C is one of the most important modifiable risk factors in reducing the risk of another cardiovascular event and studies have shown that many people who are at very high-risk, including those with ACS, are not being treated to the ACC/AHA guidelines and more intensive efforts are needed," says **Cesar Cerezo Olmos, MD, PhD**, vice president of Global and US Medical for Amgen's General Medicine business unit. "Supporting TRANSFORM: ACS represents our commitment to helping patients with cardiovascular disease improve outcomes, as well as our proactive approach to care designed to predict and help prevent another potentially life-altering CV event from happening."

This initiative is the latest under the TRANSFORM umbrella. TRANSFORM programs leverage clinical registry data, office-based interventions and partnerships to include the pharmaceutical and medical device industry, health plans, employers, clinicians and patients.

Two New Expert Consensus Decision Pathways Address HFrEF, Same-Day Discharge After PCI

The ACC has released two separate Expert Consensus Decision Pathways. The first provides guidance and recommendations on streamlining clinical care to achieve optimal outcomes for patients with heart failure with reduced ejection fraction (HFrEF) and the second addresses same-day discharge after PCI. Both were published in the *Journal of the American College of Cardiology*.

The HFrEF Pathway aims to address 10 "pivotal" issues that remain unresolved in clinical guidelines. Specifically, the Pathway looks at how to implement guideline-directed medical therapy; how to address specific challenges like referral, care coordination, specific patient cohorts, etc.; and how to manage areas of increasing complexity, comorbidities and palliative care. According to the authors, new therapies for HFrEF have emerged that expand the armamentarium for the treatment of patients with HFrEF since the original Pathway was published in 2017. As a result, the updated Pathway incorporates two new recommendations for patients with HFrEF, including the up-front use of sacubitril/valsartan without an angiotensin-converting enzyme inhibitor/angiotensin receptor blocker pre-treatment. The second recommendation is for the use of a sodium-glucose cotransporter-2 inhibitor for care of patients with HFrEF, with or without diabetes.

Scan the QR code for more.

Recent improvements in safety and efficacy have made it possible for same-day discharge to occur following PCI with select adult patients. The ACC's other new Pathway includes a checklist of clinical, social and facility/systems factors that clinicians can use to help determine whether a patient can be safely considered for same-day discharge. It also highlights the benefits of same-day discharge after PCI in leading to efficient resource utilization, including increased inpatient bed availability and reduced costs related to supplies and room and board.

Scan the QR code to access the new pathway and checklist.

NCDR: Advancing Patient Care and Outcomes

"To improve patient outcomes, we must accurately measure, reliably compare, and constantly improve the quality of care we deliver," write ACC President **Athena Poppas, MD, FACC**, and NCDR Oversight Committee Chair **Frederick A. Masoudi, MD, MSPH, FACC**, in a *JACC* Leadership Page highlighting the ways ACC's NCDR registries are consistently delivering on this aspirational goal.

In addition to helping hospitals, practices and institutions improve the care provided to patients, Masoudi and Poppas underscore the value inherent in registry-derived research, as well as the integration of education and quality improvement activities into the registry experience. They also offer a glimpse at the future of the NCDR, and a focus going forward on four objectives:

1. Reducing the burden of data collection while exploring additional sources of data.
2. Enhancing NCDR value to stakeholders.
3. Promoting local, regional, national and international quality improvement.
4. Supporting population health management through advocacy and generalizable information.

Visit *CVQuality.ACC.org* for more on NCDR, as well as ACC Accreditation Services and Quality Campaigns.

Scan the QR code to read more.

DEEP DIVE INTO THE DATA: A CLOSER LOOK AT CVD WORLDWIDE

As we approach American Heart Month, new estimates of the global burden of cardiovascular disease (CVD) increase the urgency of actions to transform cardiovascular practice and improve heart health. Learn more about these numbers from the Global Burden of Diseases, Injuries, and Risk Factors Study 2019 and what they mean for cardiovascular practice in this month's cover story starting on page 20.

30%

The percentage of smokers worldwide from China. Nearly 1/3 of all tobacco-attributable deaths occurred in China.

523 M

The number of prevalent cases of total CVD in 2019, nearly double from 271 M in 1990.

8.9 M

Total number of CVD deaths among women in 2019, compared with 9.6 M among men.

~50%

The proportion of deaths attributed to air pollution that are caused by CVD.

Source: Newman JD, Bhatt DL, Rajagopalan S, et al. *J Am Coll Cardiol* 2020;76:2878-94.

30 to 70

The age range with the greatest number of CVD deaths (6.1 M).

6-Fold

The decrease in age standardized mortality rates in Japan in 2019 compared with 1990. France and Peru joined Japan in having the lowest age-standardized mortality rates worldwide.

10

The number of underconsumed food types – fruits, vegetables, legumes, whole grains, nuts/seeds, milk, fiber, calcium, omega-3 fatty acids from seafood and polyunsaturated fats – identified by the paper. Red meat, processed meat, sugar-sweetened beverages, trans-fatty acids and sodium were the five most overconsumed food types.

8

The number of modifiable risk factors identified by the paper, including high systolic blood pressure, dietary risks, high LDL-C, air pollution, high BMI, smoking, high blood sugar and kidney dysfunction.

5

The number of countries identified by the paper with the highest number of CVD deaths (China, India, Russian Federation, U.S. and Indonesia).

Same-Day Discharge After PCI: New Expert Consensus Decision Pathway

A new ACC Expert Consensus Decision Pathway aims to address the uncertainty around same-day discharge after PCI and provides a checklist of clinical, social and facility/systems factors that clinicians can use to help determine whether a patient can be safely considered for same-day discharge.

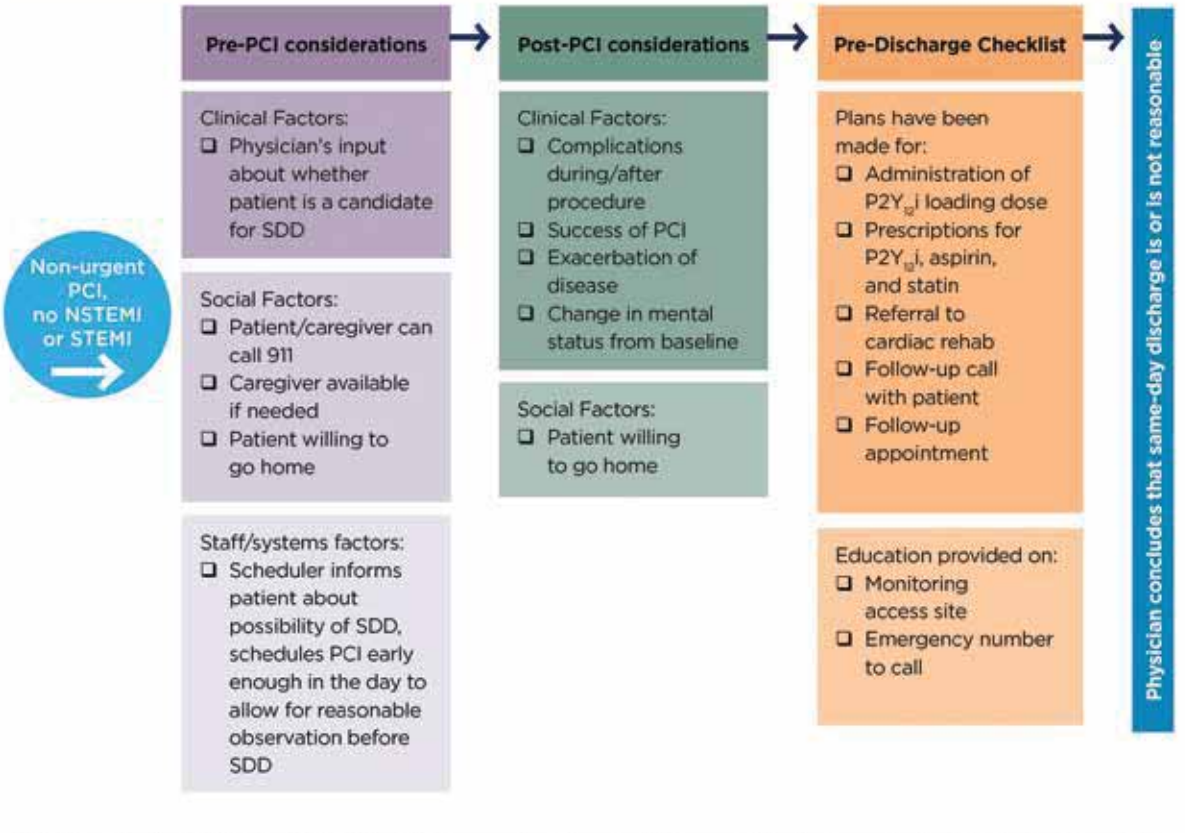
The Pathway, published in the *Journal of the American College of Cardiology*, provides an overview of the evolution of PCI and resulting improvements in safety and efficacy that make it possible for same-day discharge to occur with select adult patients without observed increases in other complications, mortality and readmissions. It also highlights the benefits of same-day discharge after PCI in leading to efficient resource utilization, including increased inpatient bed availability and reduced costs related to supplies and room and board.

The Pathway also outlines pre- and post-PCI considerations for successful same-day discharge, as well as pre-discharge processes, including confirmation of the patient's receipt of a P2Y12 inhibitor prescription, instructions on how to monitor the access site, and confirmation that the patient has appropriate outpatient follow-up scheduled.

According to the writing committee led by Chair **Sunil V. Rao, MD, FACC**, and Vice Chair **Mladen I. Vidovich, MD, FACC**, "the ideal time to begin the checklist is before the procedure, but depending on the workflow and resources of individual institutions, the checklist may also be started and completed after the procedure."

Rao, Vidovich, et al., note that the checklist is developed in a way that it can be adapted to fit the needs and processes of individual institutions. They stress that the instructions should "be adapted to conform with the protocols of individual institutions" and note that success of a same-day discharge program will be dependent on a team approach that involves shared decision-making with the patient.

FIGURE 1. Summary Graphic: Clinical, Patient, and Systems/Staff Factors to Consider Before and After PCI When Deciding on Same-Day Discharge



Graphic depiction showing the factors that affect the decision for same-day discharge for PCI. Pre-procedural and post-procedural considerations, including patient social factors, patient clinical factors, staff/system factors, and completion of discharge checklist all influence the decision on SDD.

NSTEMI = non-ST-elevation myocardial infarction; $P2Y_{12}i$ = $P2Y_{12}$ inhibitors; PCI = percutaneous coronary intervention; SDD = same-day discharge; STEMI = ST-elevation myocardial infarction.

Rao SV, Vidovich MI, Gilchrist IC, et al. *J Am Coll Cardiol* 2021;Jan 7:[Epub ahead of print].

Amyloidosis in Hospitalized HF Patients Associated With Worse Outcomes

The presence of cardiac amyloidosis in patients hospitalized with heart failure (HF) may be associated with higher rates of inpatient mortality and 30-day readmissions, according to a study published in *JACC: CardioOncology*.

Sameer Arora, MD, MPH, et al., reviewed 1,593,360 hospitalizations with a primary diagnosis of HF between 2010 and 2015. Of the patients hospitalized for HF, 2,846 (0.18%) had a secondary diagnosis of amyloidosis. These patients were then matched to 8,515 patients hospitalized for HF without amyloidosis. Of the matched patients, 63% were men and the median age was 75 years. Those with amyloidosis were more likely than those without amyloidosis to have malignancy (20% vs. 4%) and kidney disease (56% vs. 45%). Patients with amyloidosis had lower prevalence of chronic pulmonary disease, diabetes, history of myocardial infarction, peripheral vascular disease, coronary artery disease, hypertension and obesity.

Results showed that the primary outcome of inpatient mortality was 6% in patients with amyloidosis vs. 3% in those without amyloidosis. Among those with amyloidosis, 30-day readmission was 24% vs. 21% in those without. In unadjusted analysis, HF with amyloidosis was associated with higher odds of in-hospital morality (odds ratio [OR], 1.46; 95% confidence interval [CI], 1.17-1.82) and 30-day readmissions (OR, 1.17; 95% CI, 1.05-1.31).

The increased likelihood of readmission in those with amyloidosis was largely driven by readmission for noncardiovascular reasons. There was no significant between-group difference in cardiovascular-related readmissions. Patients with amyloidosis had a longer length of stay.

"With the advent of new life-prolonging therapies for cardiac amyloidosis, these results emphasize the need to develop more effective screening strategies to facilitate early diagnosis of amyloidosis in HF patients," conclude the study authors.

They study confirms that amyloidosis "is significantly underdiagnosed among patients admitted with decompensated HF," **Karen E. Joynt Maddox, MD, MPH, FACC**, and **Kathleen W. Zhang, MD, FACC,** write in an accompanying editorial comment. They add that "a national effort is needed to better care for these patients, who are at high risk for missed diagnosis and treatment."

Arora S, Patil NS, Strassle PD, et al. *JACC CardioOncology* 2020;2:710-8.

Call For Papers:
Heart Failure and Diabetes

JACC: Heart Failure invites submissions for a focus issue on diabetes and heart failure planned for August of 2021. Submissions are due April 2. Learn more in the new *JACC Journals Author Center* at *JACC.org/Author-Center* or scan the QR code.

How is Cardio-Oncology Advancing in Japan?

Cancer and cardiovascular disease are the leading causes of death in Japan, a country with a rapidly increasing elderly population. While Japan has made progress in reducing cancer mortality, there has been an increase in the number of cancer survivors. Consequently, Japan is seeing an increase in cardiovascular events related to cancer treatment. To address the growing field of cardio-oncology in Japan, **Issei Komuro, MD, PhD,** president of the Japanese Onco-Cardiology Society, published two perspectives Dec. 15 in *JACC: CardioOncology*.

In the first paper, Komuro and **Chikashi Ishioka, MD, PhD**, president of the Japanese Society of Medical Oncology, discuss the growing demand for treatment of cancer patients with cardiovascular comorbidities or complications. They explain that cardiologists need information and knowledge of current cancer therapies; and in turn, oncologists require the same information and knowledge of cardiovascular disease. The Japanese Onco-Cardiology Society was established in 2017 to further strengthen collaboration between cardiologists and oncologists to move cardio-oncology forward. The medical societies led by Komuro and Ishioka will continue to work together to create registries and increase an exchange of views between cardiologists and oncologists to design and conduct studies, as well as develop evidence-based guidelines for cardio-oncology. "Our societies will continue efforts to reduce the growing burden of cardiovascular disease and cancer and to make cardio-oncology blossom in Japan," they write.

In the second paper, Komuro, **Toru Oka, MD, PhD,** et al., discuss how Japan has focused on reducing the burden of cancer by creating 402 cancer hospitals since 2007. In 2010, the first "onco-cardiology" unit was launched as part of growing awareness of the cardiovascular impacts on outcomes and quality of life in cancer patients and survivors. Since the inaugural unit, cardio-oncology units have become more widespread in Japan. Medical societies within the country are working together to further establish these units to provide high-quality medical care and coordinate medical education, training and research across the globe. According to the authors, "the importance of cardio-oncology will definitely continue to increase more and more in Japan, where an epidemic of cancer and cardiovascular disease is emerging because of the aging of the population."

Komuro I, Ishioka C. *JACC CardioOncology* 2020;2:819-21.
Oka T, Akazawa H, Sase K, et al. *JACC CardioOncology* 2020;2:815-8.

Are HF Patients Hospitalized With COVID-19 At Greater Risk of Death?

Nearly one in four patients with heart failure (HF) hospitalized with COVID-19 die during hospitalization, based on findings from a study published in *JACC: Heart Failure*. Study authors note their results highlight the need for "targeted infection control measures and novel care pathways" in this high-risk group.

Ankeet S. Bhatt, MD, MBA, Karola S. Jering, MD, et al., analyzed data from 132,312 patients in the Premier Healthcare Database with at least one hospitalization for HF or two HF-related outpatient visits between Jan. 1, 2019 and March 31, 2020, and who were subsequently hospitalized between April and September 2020. Researchers compared baseline characteristics, health care resource utilization and mortality rates between those patients hospitalized for COVID-19 and patients hospitalized for other causes. Multivariate logistic regression was used to identify predictors of in-hospital mortality.

Results found a total of 23,843 patients (18%) were hospitalized with acute HF, 8,383 patients (6.4%) were hospitalized with COVID-19 and 100,068 patients (75.6%) were hospitalized for other causes between April and September 2020. Of those patients hospitalized with COVID-19, 24.2% died in the hospital vs. 2.6% of those hospitalized with acute HF. According to the authors, advanced age, morbid obesity and diabetes were among the predictors of death in HF failure patients hospitalized with COVID-19.

"Hospitalization with COVID-19 in patients with [HF] is associated with particularly high health care resource utilization and in-hospital mortality," the authors wrote. They stress the importance of "structured data collection to determine COVID-19 prevalence across ongoing and planned randomized clinical trials in [HF]" moving forward and note "the prevalence of COVID-19 in each individual trial may drastically influence interpretation of regulatory trial data."

In a related editorial comment, **Ersilia M. DeFilippis, MD, Mitchell A. Psotka, MD, PHD, FACC**, and **Nasrien E. Ibrahim, MD, FACC**, write that patients with HF in the study who were hospitalized for COVID-19 "were more likely to identify as Black and/or Hispanic, consistent with previous evidence of the disproportionate burden of COVID-19 infection on underrepresented minorities."

Bhatt AS, Jering KS, Vaduganathan M, et al. *JACC Heart Fail* 2021;9:65-73.

Does Increasing Female, Minority Mentors Increase Success and Diversity in Cardiology?

Efforts to increase the number and visibility of female and underrepresented minority cardiology mentors may have the potential to shift the demographics within the field of cardiology and lead to increased diversity and sex balance, according to a paper published in *JACC: Basic to Translational Science*.

Islam Abudayyeh, MD, MPH, FACC, et al., conducted a survey of ACC cardiologists to assess career mentor activity and success, as well as identify the areas of greatest need. The survey was completed by 508 cardiologists. Questions focused on demographics, mentor experience, metrics of success, professional development and job satisfaction.

Results showed that mentees are more satisfied with their mentorship experience when they have had more than three mentors or a mentor from outside of their practice or institution. The authors note that a higher number of mentors may reflect an increased likelihood of finding a "good fit" mentor, and that having a mentor outside of one's institution may reflect increased networking. In addition, the characteristics that mentees desire in a mentor tended to change with time and career stage.

Importantly, survey results also showed that satisfaction with the mentoring relationship is significantly associated with perceived satisfaction in achieving professional goals.

Furthermore, the authors found that gender and race concordance in mentoring relationships was associated with positive outcomes, as well as an important variable to increase diversity in cardiology.

"Although our findings also support sex and race/ethnic concordance in mentoring relationships, sample sizes were small for some subgroups," the authors conclude. "Thus, additional research is needed to more thoroughly investigate the effect of sex and race on mentoring, career success, and professional satisfaction."

Abudayyeh I, Tandon A, Wittekind SG, et al. *JACC Basic Transl Science* 2020;5:1181-6.

How Do Health Outcomes of Wealthy White Americans Compare With Average U.S. Citizens and Other Countries?

While health outcomes of White Americans living in the richest counties are better than those of average U.S. citizens, the outcomes are not consistently better than those of average residents in many other developed countries, according to findings from a comparative effectiveness study published in *JAMA Internal Medicine*.

"Even if everyone achieved the health outcomes of White US citizens living in the 1% and 5% richest counties, health indicators [in the US] would still lag behind those in many other countries," the study authors write.

The study conducted by **Ezekiel J. Emanuel, MD, PhD, Emily Gudbranson, BA,** et al., analyzed data from White citizens living in the 1% (n=32) and 5% (n=157) highest-income counties in the U.S. between Jan. 1, 2014 and Dec. 31, 2015 and measured health outcomes related to infant and maternal mortality, colon and breast cancer, childhood acute lymphocytic leukemia, and acute myocardial infarction (AMI). These data were then compared with outcomes among average U.S. residents and all residents in 12 other developed countries, including Australia, Austria, Canada, Denmark, Finland, France, Germany, Japan, the Netherlands, Norway, Sweden and Switzerland.

Overall findings showed White U.S. citizens in the 1% and 5% highest-income counties obtained better health outcomes than average U.S. citizens, but had worse outcomes for infant and maternal mortality, colon cancer, childhood acute lymphocytic leukemia and AMI compared with average citizens of other developed countries.

The authors note that the 5-year survival rate for breast cancer among White U.S. women in the highest-income counties was 92.0%, higher than in all 12 comparison countries – likely due to the push for mammogram screenings in the U.S.

According to the authors, their findings underscore that being well off and White in the U.S. are associated with better health outcomes than those experienced by average US citizens, yet at the same time being well off and White does not guarantee the world's best health outcomes.

They also point out that "even if the dramatic and pervasive inequalities in the provision of U.S. health care across race/ethnicity and socioeconomic status were resolved so that every U.S. citizen experienced health outcomes consistent with those of privileged U.S. citizens, the U.S. would still not rank among the best of comparison countries." They write these findings "suggest — but do not prove — that health outcomes depend on the system of care, rather than the performance of individual physicians or hospitals."

Emanuel EJ, Gudbranson E, Van Parys J, et al. *JAMA Intern Med* 2020;Dec 28:[Epub ahead of print].

JAMA Viewpoint Underscores Disproportionate Number of Black Men and Women in Medicine

"The disproportionate effect of the novel coronavirus on African Americans and communities of color has shone a new light on the more than century-old struggle to increase the number of Black physicians in the U.S.," writes **Valerie Montgomery Rice, MD,** in a viewpoint published in *JAMA*.

According to Montgomery Rice, president and dean of Morehouse School of Medicine in Atlanta, GA, "the U.S. has failed to adequately increase the number of Black physicians since the turn of the 20th century," with total Black enrollment in U.S. medical schools hovering around 7% since 2013.

Among the barriers to medical school enrollment for underrepresented minorities is the Medical College Admission Test (MCAT). According to Montgomery Rice "the MCAT score has not been shown to significantly predict whether students will successfully progress in their medical education," yet has an adverse influence on Black applicants. She writes: "More medical schools should focus less on their rankings, such as in the *US News and World Report,* and should more intentionally embrace their stated missions of diversity and inclusion, using MCAT scores as only one determinant in the selection process, and admitting more of these students. This approach could potentially lead to 3,000 more Black physicians either practicing or in the training pipeline in the U.S. today."

In a related editorial, **Clyde W. Yancy, MD, MACC,** and **Howard Bauchner, MD,** call for a bold new model to fully address diversity in medicine that includes establishing a new medical school at a historically Black college and university. "This new medical school concept provides a needed near-term solution that definitely enhances capacity and, when added to the ongoing commitment to increase diversity in existing medical schools, amounts to real change," they write. They note the challenge will be summoning the will to do it, but stress that the current system as configured will continue to fail with a "significant increase in capacity and a bold and different approach."

Montgomery Rice V. *JAMA* 2021;325:23-4.

Use of MV PCI Increases, But Still Used in Minority of STEMI Patients, NCDR Study Finds

Use of multivessel (MV) PCI among STEMI patients increased through early 2018, but was used in a minority of patients and with wide variations across the U.S., according to a study published in *JAMA Cardiology*. The study is part of ACC's Research to Practice (R2P) initiative, which identifies impactful cardiovascular research and analyzes its implications for contemporary clinical practice using ACC's NCDR clinical registries.

Eric A. Secemsky, MD, FACC, et al., used data from ACC's CathPCI Registry to examine temporal trends and institutional variation in use of MV PCI among patients with STEMI and MV disease. The researchers looked at all admissions between July 2009 and March 2018 in which patients received primary PCI for STEMI within 12 or fewer hours of presentation or PCI within 24 or fewer hours of thrombolysis and also had MV disease.

Among all STEMI admissions, 359,879 (35.2%) were included in the study. Of these, 138,380 (38.5%) received MV PCI within 45 days. Among patients receiving MV PCI, 42,629 (30.8%) were performed during the index procedure, 43,696 (31.6%) during the index hospitalization and 52,055 (37.6%) within 45 days. Complete revascularization was performed in 105,389 (76.2%) of those who underwent MV PCI. Use of MV PCI declined by 10% from the third quarter of 2009, when the rate was 42.7%, to the second quarter of 2013, with the rate was 32.7%, followed by an increase to 44% in the fourth quarter of 2017. The authors found substantial variation in the in MV PCI across institutions, with a median use of 37.9%.

MV PCI use increased during the study period, but was used in a minority of patients and with wide variations across institutions, the researchers explain. They conclude that moving forward, "continued adoption of new trial results into guidelines and practice may further promote the growth of MV PCI."

In an accompanying editorial commentary **John A. Bittl, MD, FACC,** notes that the difference of 11 percentage points between the periods with lowest and highest uptake of MV PCI "probably reflects the belief throughout all periods that culprit-only PCI is the default strategy, with preemptive PCI on nonculprit vessels being reserved for special circumstances." He adds that Secemsky, et al., "should be commended for showing that culprit-only PCI is the preferred approach in practice and routine multivessel PCI is unpropitious."

Secemsky EA, Butala N, Raja A, et al. *JAMA Cardiol* Nov 4:[Epub ahead of print].

Visit *ACC.org/Latest-in-Cardiology* for additional journal coverage, including Journal Scans and Trial Updates, handpicked weekly by the *ACC.org* Editorial Board led by **Kim Eagle, MD, MACC.**

Vaping Plus Smoking as Harmful as Smoking Alone

Smoking traditional cigarettes in addition to using e-cigarettes results in harmful health effects similar with smoking cigarettes exclusively, according to a study published in *Circulation*.

In a data analysis of more than 7,100 U.S. adults ages 18 and older, researchers studied the association of cigarette smoking and e-cigarette use with biomarkers of inflammation and oxidative stress, key contributors to smoking-induced cardiovascular disease.

Of the study participants, 58.6% did not use cigarettes or e-cigarettes; nearly 2% vaped exclusively; about 30% smoked cigarettes exclusively; and about 10% used e-cigarettes and traditional cigarettes.

The results found a similar inflammatory and oxidative stress profile in participants who vaped exclusively and those who did not smoke cigarettes or use e-cigarettes. Higher levels across all biomarkers were seen in participants who smoked exclusively and those who used cigarettes plus e-cigarettes vs. those who never used either.

"I believe [this study] has an important message for individuals who may believe using e-cigarettes while continuing to smoke some combustible cigarettes reduces their risk," says study co-author **Rose Marie Robertson, MD, FACC.**

Xi W, Wilson A, Yang H, et al. *Circulation* 2020;2020;Jan 4[Epub ahead of print].

Subcutaneous ICDs Increasing in Dialysis Patients With Low Complication Rates, NCDR Study Shows

Use of subcutaneous ICDs in dialysis patients has been steadily increasing, with overall low complication rates compared with transvenous ICDs, according to a study published in the *Clinical Journal of the American Society of Nephrology.*

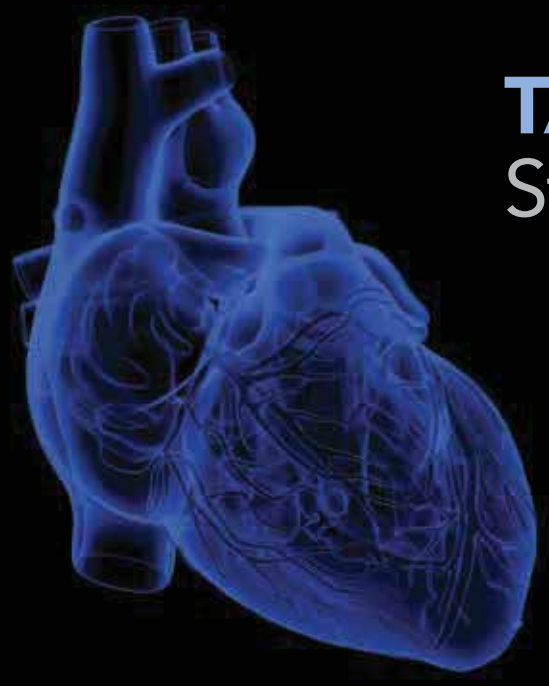
Patrick H. Pun, MD, et al., used data from ACC's ICD Registry to examine overall trends in subcutaneous ICD adoption among eligible dialysis patients between September 2012 – when subcutaneous ICDs first became available – and March 2018, and compare in-hospital outcomes among dialysis patients receiving subcutaneous ICDs vs. transvenous ICDs. For the comparative analysis, the researchers limited the cohort to only dialysis patients who met criteria for a subcutaneous ICD and were hospitalized for an elective first-time ICD implantation. The primary outcome was the composite of any in-hospital adverse events.

During the study period, there were 23,135 ICD implantations among dialysis patients. Of these patients, 3,195 (14%) received subcutaneous devices. Subcutaneous devices accounted for about 5% of all ICD implantations at the beginning of the study, compared with 20% of all ICD implantation procedures in 2018.

For the comparative analysis, there were 1,539 patients who received subcutaneous ICDs and 1,788 who received transvenous ICDs. Among these patients, use of subcutaneous devices increased from 10% of all implants in 2012 to 69% of all implants in 2018. Before propensity scoring, subcutaneous ICD recipients were younger, more likely to be Black, and less likely to be from southern states. The composite of any in-hospital adverse event was not statistically different between those receiving subcutaneous ICDs (2.39 events per 100 implantations) vs. transvenous ICDs (1.48 events per 100 implantations). However, patients receiving subcutaneous devices were more likely to experience in-hospital cardiac arrest vs. those receiving transvenous ICDs.

According to the researchers, the study shows an overall low complication rate in dialysis patients who receive subcutaneous ICDs. While the low complication rate supports use of subcutaneous devices in eligible dialysis patients, they note that "potential benefits of lower long-term infection risk and reduction in central venous stenosis, compared with transvenous ICD, have not been proven." Moving forward, longer-term studies are needed to determine the risk-benefit and cost-effectiveness of subcutaneous ICDs in this population, they conclude.

Pun PH, Parzynski CS, Friedman DJ, et al. *Clin J Am Soc Nephrol* 2020;Nov 6:[Epub ahead of print].



TAVR and SAVR: Different Strategies For Different Folks?

Transcatheter aortic valve replacement (TAVR) for high-risk, older patients with severe aortic stenosis is now standard therapy. Its expanded use in other patient populations – including younger patients with lower risk – has been tested in several randomized trials. Many now think that TAVR should be a universal therapeutic first choice – but do the data really support this stance? This month *Cardiology* takes a look at the evidence for determining which patients are best suited for TAVR, based on what the data show, and which patients are perhaps still better served by surgical aortic valve replacement (SAVR).

TAVR: From Then Until Now

In a little less than a decade, we have experienced a major paradigm shift in the management of patients with severe, symptomatic aortic stenosis (AS). Starting in 2011, with the first commercial approval of TAVR by the U.S. Food and Drug Administration (FDA), more than 300,000 patients have been treated in the U.S.

Although it currently seems as if a tsunami is occurring, actually it has been a 31-year journey since the initial idea was conceived by **Henning Andersen, MD, PhD,** a cardiologist in Aarhus, Denmark. Milestones along this journey include the first series of animal implantations that were presented as a poster at the European Society of Cardiology Congress in 1992, the first human TAVR implantation by **G. Alain Cribier, MD,** in Rouen, France, in 2002 and the first U.S. experience in 2004.

The Evidence

In the U.S., two series of investigational device exemption (IDE) randomized trials leading to FDA approval started in 2007. These regulatory approval trials, the PARTNER trials of the balloon-expandable Sapien Valve (Edwards Lifesciences, Irvine, CA) and the CoreValve/Evolut Trials (Medtronic, Inc., Minneapolis, MN) of a self-expanding valve led to the initial FDA approval of TAVR in 2011 and reimbursement coverage by the Centers for Medicare and Medicaid Services (CMS) in 2012.

These series of trials have enrolled a total of 9,682 patients, of which 8,098 have been randomized to TAVR with a control of either medical therapy or SAVR. This has resulted in a robust evidence base that led to hundreds of peer reviewed publications, including 10 articles in the *New England Journal of Medicine* and two in *The Lancet*.

The two series of trials started in inoperable patients, finding that TAVR was superior to medical therapy. The subsequent trials in high risk and intermediate surgical risk patients all found that TAVR was noninferior to SAVR. The latest of the trials in patients with low surgical risk presented and published in 2019, found that TAVR was either superior to or noninferior to SAVR at one and two years.[1,2] Ten year follow-up is planned for both trials.

Figure 1 Low-Risk Patients Receiving TAVR in the "Real-World vs. Pivotal Trials

	TVT Registry	Low Risk Trial #1	Low Risk Trial #2
Number of Patients Receiving TAVR	8,385 in 2019 (7,101 in 2nd half of 2019)	496 (as treated cohort)	725 (as treated cohort)
Age of Patients	Median 75 years (IQR 70,81)	Mean 73 years	Mean 74 years
Sex	65% Male	67.5% Male	66% Male
Race	93% White	NA	92% White
STS PROM Score	Median 2.3% (IQR 1.6, 3.45)	Mean 1.9%	Mean 1.9%
Baseline NYHA Class 3 and 4	48.9%	31.2%	25.1%
Femoral Access	97.8%	100%	100%
Length of Hospital Stay	Median 1 (IQR 1,2)	Mean 3 days	NA
In-Hospital Mortality	0.5%	0.4%	NA

The Now

All commercially implanted TAVR devices in the U.S., with the exception of government hospitals, are entered into the STS/ACC TVT Registry, a condition of reimbursement by a National Coverage Determination (NCD) issued by CMS.

According to registry data, there are currently 716 centers in the U.S. performing TAVR, and in 2019 there were approximately 75,000 patients treated.[3] The demographics and outcomes of patients treated in the real-world setting largely mirrors those patients treated in the pivotal trials (**Figure 1**). It was estimated that there would be a 20-25% further increase in TAVR implantations in 2020 resulting in a total of 90,000 to 100,000 patients undergoing the procedure. However, the impact of the COVID-19 pandemic has attenuated that continued procedural growth by an estimated 20%.

The Candidates

Based on trial evidence, the decision regarding appropriate candidates for TAVR should no longer be based on the patient's risk for a surgical procedure. Rather, the patient's age should be the basis for the initial decision (**Figure 2**).

In a possible decision pathway, the first decision is to determine whether the patient is better suited for a tissue valve or a mechanical valve. Current guidelines recommend a mechanical valve for patients <55 years and a tissue valve for patients >65 years with shared decision-making based on patient's preference being the determining factor in patients between 55 and 65 years.[4]

If a patient is deemed to be best suited for a tissue valve, the next decision is determining whether the patient is best treated by TAVR or SAVR. There were very few patients younger than 65 years (<10%) enrolled into any of the low risk TAVR trials, so we lack a robust body of evidence in younger patients. Currently most patients >80 years are best treated with TAVR and those 65

years or younger by SAVR, with individual patient preferences and patient comorbidities and valve path-anatomic factors informing the decision in for patients between 65 and 80 years.

The path-anatomic factors for consideration in patients 65 and 80 years include trial exclusions such as patients with bicuspid aortic valves, extensive left ventricular outflow tract calcium, asymptomatic patients and those with complex concomitant coronary artery disease. Therefore, SAVR should be the preferred approach in these patients who have a reasonable surgical risk. In addition, other patients who are at high risk for TAVR include those with low-lying coronary artery orifices or requiring an alternative access approach and there should be strong consideration for SAVR.

The Unanswered Questions

Other evidence gaps regarding TAVR to be addressed include the greater need for a new permanent pacemaker, which becomes more important in younger patients, and a higher incidence of new left bundle branch block which has been determined to be a risk factor for long-term mortality.

The issue of valve thrombosis and need for anticoagulation is another unanswered question. In a recent FDA-mandated CT substudy of the low-risk trials, there was imaging evidence of valve thrombus in 20-28% of patients undergoing both TAVR and SAVR by one year.[5] Most of these were not associated with a clinical event and the need for anticoagulation remains unclear. A recent trial of rivaroxaban in TAVR was stopped early due to safety issues, yet a 4D CT substudy of this trial showed there was a lower incidence of valve thrombosis in the treatment arm.[6,7]

Durability is yet another unanswered concern. Currently, there is no significant signal of structural valve deterioration up to five years. However, very few patients are alive after five years, although some patients in the NOTION trial have been followed to eight years. In the patients in the low-risk TAVR trials, we only have two-year follow-up data. But all these patients will be followed annually for 10 years to help answer the question of the durability of tissue valves in both TAVR and SAVR.

The use of TAVR in bicuspid aortic valves, especially in younger patients, remains an evidence gap. And it remains to be determined what evidence will be generated to indicate which patients with bicuspid aortic valves can be treated safely with TAVR and which patients should be preferentially treated with SAVR.

The Role of SAVR

Despite the widespread adoption of TAVR, SAVR will continue be a necessary and important part of the treatment of patients with aortic stenosis (**Figure 3**). It is estimated that in the near future, one of three or four patients undergoing aortic valve replacement will still be best treated with SAVR. This includes patients with extensive coronary artery disease, other valvular disease, dilation of the ascending aorta, young patients with bicuspid aortic valves and, of course, endocarditis.

The next few years will also see an increasing number of patients presenting for a surgical procedure after a previous TAVR. Early experience with surgery in these patients indicates that the complexity of the surgical procedure will be greater when explantation of a TAVR device is necessary.

Summary

In a little less than a decade, we have seen a major paradigm shift in the management of aortic stenosis. It has been truly remarkable to see the rapid adoption of a procedure that is widely applicable to a large number of patients who are able to be treated in a safe and effective manner by a broad cadre of practitioners.

Figure 2 Possible Clinical Decision Making in Aortic Stenosis

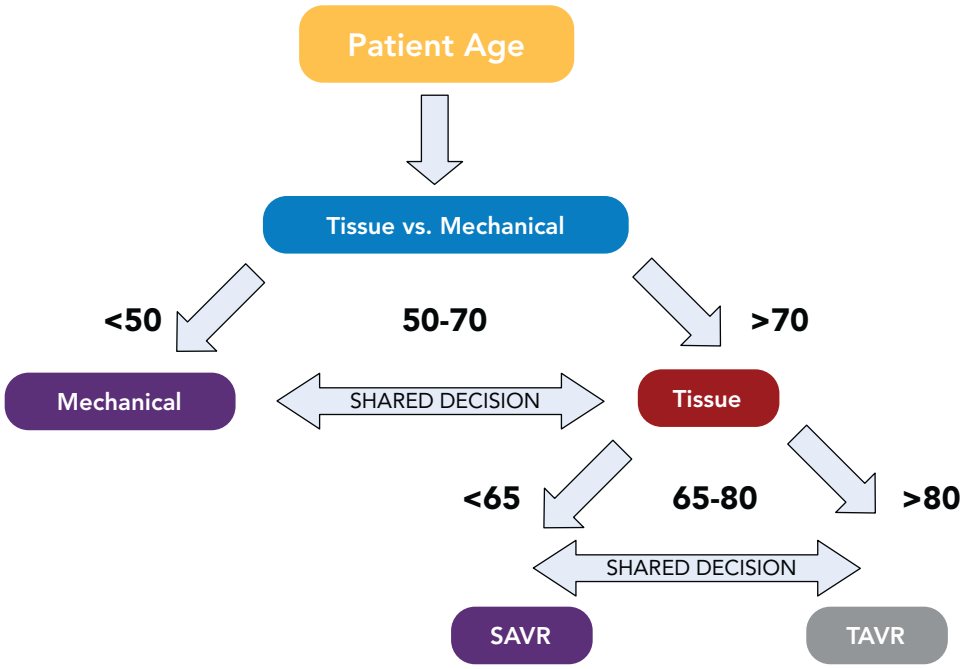
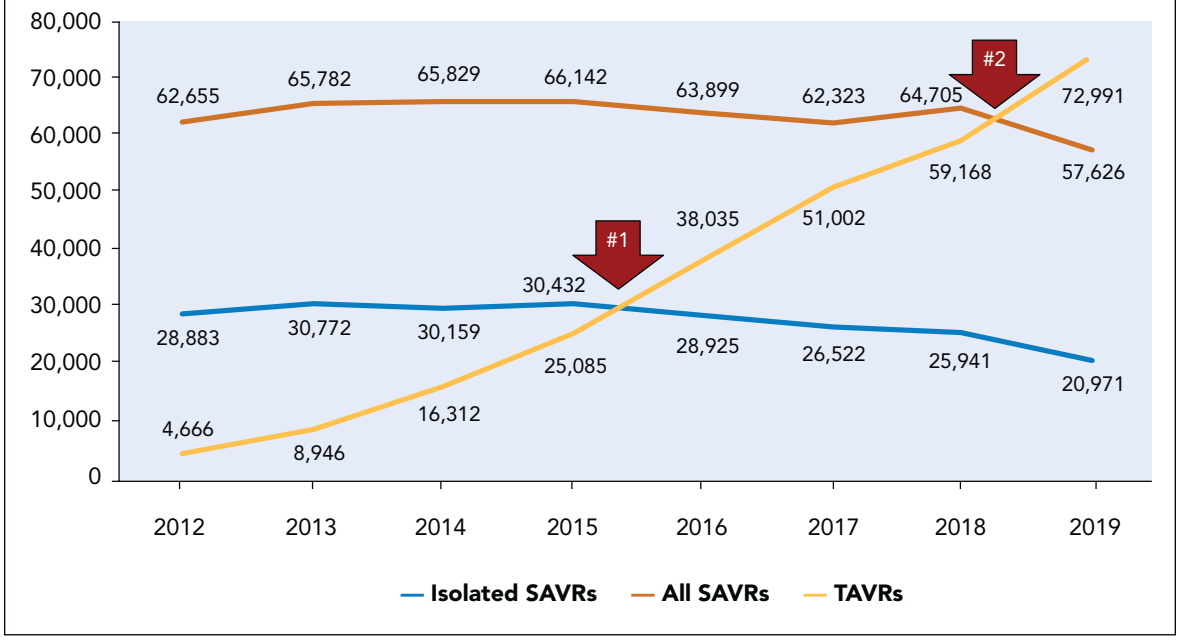


Figure 3 Rates of TAVR and SAVR From 2012 to 2019



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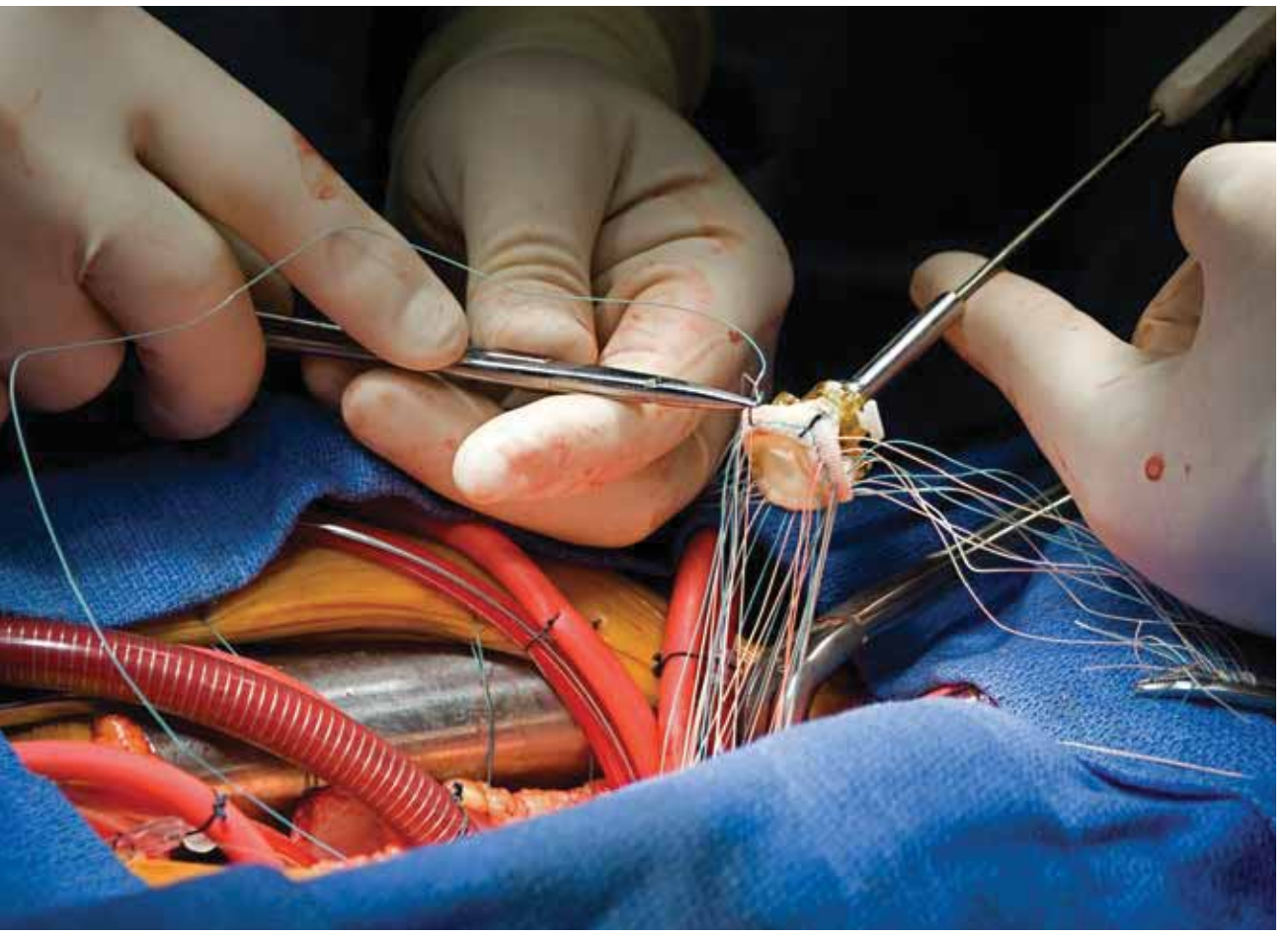
Structural Heart Disease Intervention: Quo Vadis?

Interventional therapies for cardiac pathology have advanced at a rapid and accelerating rate during the last decade and are now legion. During the latter half of the last century there was a rapid expansion of surgical solutions which more recently have been standardized, promoting reliable and durable results. This is now the era of safe and reproducible surgery.



The advent of minimal access and percutaneous procedures have altered the landscape irreversibly, often, but not always for the good. The trend towards the apparent universal dissemination of coronary angioplasty and stenting applied in a staged approach has been replaced by the demonstration of the superiority of surgery in certain defined groups; this, plus the advent of the "heart team" operating within the confines of a good evidence base has resulted in a balanced approach with a more appropriate use of surgery and catheter-based procedures to the betterment of patient outcomes.

A new revolution is happening now in the management of heart valve disease. Effective therapies for the mitral and aortic valves are evolving quickly and whilst short-term outcome data are being generated and published, some in the form of randomized-controlled trials, meaningful mid- to long-term data (five to 15 years) is absent. Conversely, while the vast surgical experience is short on controlled prospective data, it is replete with long-term of the performance of most important extant valve types.

Data at 15 and 20+ years are available for valve replacement and valve reconstruction. A great deal is known about prosthetic valve function and deterioration, the incidence of significant para-prosthetic leaks and patient-prosthesis mismatch. Current mortality should be very low with rates of less than 1% mortality and six days or less length of hospital postoperative stay being almost the rule in good centers, and excellent and durable quality of life is now the norm. However, all is not perfect. Remember, the elephant in the room is there is no such thing as "surgery," there are only "surgeons" and their results are variable. Hence the need for specialist centers.

Variable results between surgeons and centers continue and poor surgery results in the complications raised above. A recent paper reported a mortality of 3.6% for SAVR in a study which contrasted this with the results for TAVR, portraying SAVR in a poor light.[1] However, the quoted incidence of mortality is at a level that would cause horror in quality institutions. (Current mortality for all-comers for AVR in our hospital runs at 0.8% and we believe this can be improved upon). Hospital length of stay is an average of five days and para-prosthetic leaks and early valve failure are rare. Contrast this with TAVR where mortality is also low, but para-prosthetic leaks and pacemaker use are high and mid- to long-term failure rate remains largely unknown.

In the mitral arena, reconstructive surgery of the "degenerative" valve is now the norm in most expert centers where expertise is focused in fewer, expert hands. Repair rates exceeding 90% are expected with a mortality of less than 1%.[1] Mitral valve replacement with complete subvalve preservation is similarly an excellent procedure with well-defined and excellent long-term outcomes.

Into this arena steps percutaneous interventions that are as yet not well tested outside a few specialist centers. The Mitraclip, where the opposing leaflets are fixed together producing a double-orifice valve, has now secured approval in some countries and institutions. Its initial use has been in patients otherwise deemed too high risk for surgery and patients with functional mitral regurgitation resulting in satisfactory initial results in controlling and/or reducing the amount of mitral regurgitation. However, several learning points from the surgical groups are being ignored. One is that ischemic mitral regurgitation is a ventricular disease which will progress as ventricular degeneration continues causing a return of mitral regurgitation. With a surgical approach, multiple procedures exist to mitigate against this including annuloplasty, papillary muscle approximation and ventricular wall plication. Indeed, the most recent studies have shown superiority of mitral valve replacement with subvalvular preservation in the worst cases.

Its move into degenerative cases is being enhanced by poorly controlled mitral valve surgery in some centers where repair in even infirm elderly patients can be achieved with excellent permanent results in the correct surgical hands. It can be argued that all of this reveals a focus on the careers of some professionals rather than what is best for patients. One has to ask how much professional empowerment and perhaps arrogance plays over the Hippocratic stance of first do no harm on both sides of this particular fence.

Thus, what should be the way ahead? First, the use of such devices is discussed by a well-informed heart team. Second, ready access to the evidence base. Third, the prospective collection of all data. With this in place, the best plan for each patient can be formed. Finally, it is vital that the patient is given a full review of the discussion surrounding their case, not "edited highlights" to enable them to make the best decision for themselves.

And, cardiologists, do not forget that the more routine surgery keeps surgeons in practice for the more difficult problems whence many patients will still need their skills.

Editor's Note: Turn to page 2 for an editorial on patient selection for TAVR and pages 34-35 for recommendations for TAVR and more from the newly released ACC/AHA Guideline on Valvular Heart Disease.

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This article was authored by **Francis C. Wells, MBBS,** cardiac surgeon at Royal Papworth Hospital and Cambridge University, Cambridge, England.

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Mount Vernon, IL

Red Bud Regional Hospital
Red Bud, IL

St. Mary Medical Center
Hobart, IN

Providence Medical Center
Kansas City, KS

Salina Regional Health Center
Salina, KS

The University of Kansas Health System St. Francis Campus
Topeka, KS

Ephraim McDowell Regional Medical Center
Danville, KY

Spring View Hospital
Lebanon, KY

St. Mary's Medical Center
Blue Springs, MO

Saint Joseph Medical Center
Kansas City, MO

Mosaic Life Care at St. Joseph
St. Joseph, MO

Billings Clinic
Billings, MT

Community Medical Center
Missoula, MT

Dignity Health-St. Rose Dominican, Siena Campus
Henderson, NV

Dignity Health-St. Rose Dominican, San Martin Campus
Las Vegas, NV

North Vista Hospital
Las Vegas, NV

Saint Mary's Regional Medical Center
Reno, NV

Hackensack University Medical Center
Hackensack, NJ

New York-Presbyterian Lawrence Hospital
Bronxville, NY

Central Carolina Hospital
Sanford, NC

Davis Regional Medical Center
Statesville, NC

East Liverpool City Hospital
East Liverpool, OH

Trumbull Regional Medical Center
Warren, OH

Willamette Valley Medical Center
McMinnville, OR

Doylestown Hospital
Doylestown, PA

St. Luke's Hospital - Lehighton Campus
Lehighton, PA

Conemaugh Meyersdale Medical Center
Meyersdale, PA

Conemaugh Nason Medical Center
Roaring Spring, PA

St. Luke's Hospital - Monroe Campus
Stroudsburg, PA

Chester County Hospital
West Chester, PA

Wilkes-Barre General Hospital
Wilkes-Barre, PA

Kershaw Medical Center
Camden, SC

Greenville Memorial Hospital
Greenville, SC

Carolina Pines Regional Medical Center
Hartsville, SC

Erlanger Medical Center
Chattanooga, TN

Medical City Heart and Spine Hospitals
Dallas, TX

Medical City Dallas Hospital
Dallas, TX

Dallas Regional Medical Center
Mesquite, TX

Palestine Regional Medical Center
Palestine, TX

Sovah Health – Martinsville
Martinsville, VA

Riverside Regional Medical Center
Newport News, VA

Fauquier Hospital
Warrenton, VA

Shenandoah Memorial Hospital
Woodstock, VA

Wythe County Community Hospital
Wytheville, VA

Raleigh General Hospital
Beckley, WV

Logan Regional Medical Center
Logan, WV

WVU Medicine Camden Clark Medical Center
Parkersburg, WV

Aurora Medical Center in Grafton
Grafton, WI

Aurora St. Luke's Medical Center
Milwaukee, WI

Aurora Medical Center in Summit
Summit, WI

Watertown Regional Medical Center
Watertown, WI

Samaritano Paulista
São Paulo, Brazil

CARDIAC CATH LAB ACCREDITATION

Shelby Baptist Medical Center
Alabaster, AL

Indiana University Health Methodist Hospital
Indianapolis, IN

Exeter Hospital
Exeter, NH

Wilkes-Barre General Hospital
Wilkes-Barre, PA

HEART FAILURE ACCREDITATION

Christus St Frances Cabrini Hospital
Alexandria, LA

Lawrence General Hospital
Lawrence, MA

Spartanburg Medical Center
Spartanburg, SC

TRANSCATHETER VALVE CERTIFICATION

Palomar Medical Center
Escondido, CA

Sutter Medical Center Sacramento
Sacramento, CA

UCHealth Memorial Hospital
Colorado Springs, CO

Saint Joseph Hospital
Denver, CO

North Colorado Medical Center
Greeley, CO

Sarasota Memorial Hospital
Sarasota, FL

Franciscan Health Indianapolis
Indianapolis, IN

UnityPoint Health - St. Luke's Hospital
Cedar Rapids, IA

Norton Audubon Hospital
Louisville, KY

Morristown Medical Center
Morristown, NJ

The Mount Sinai Hospital
New York, NY

Strong Memorial Hospital
Rochester, NY

St. Rita's Medical Center
Lima, OH

St. John Medical Center
Tulsa, OK

Regional Hospital of Scranton
Scranton, PA

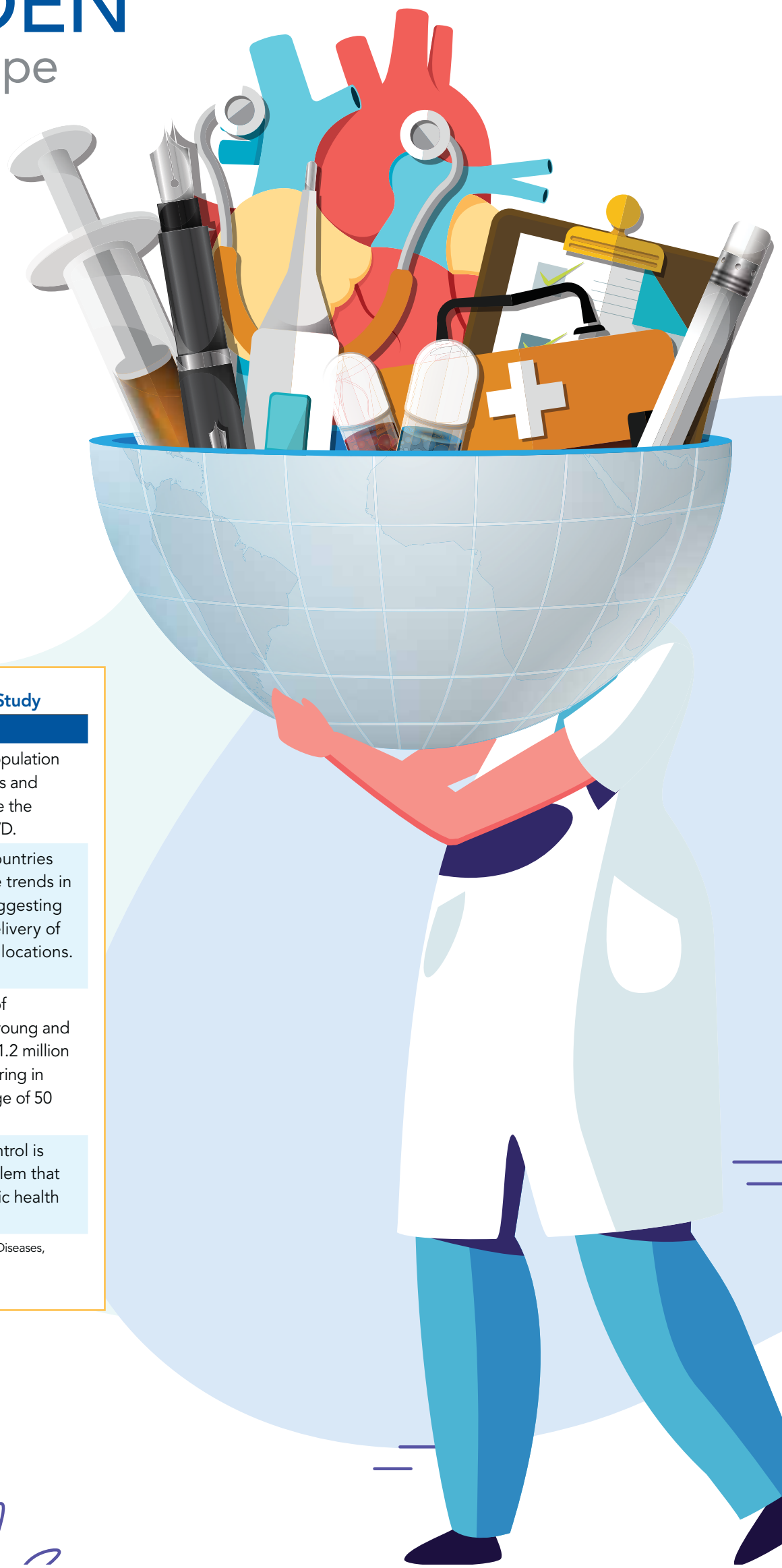
Lexington Medical Center
West Columbia, SC

Jackson-Madison County General Hospital
Jackson, TN

Ascension Providence
Waco, TX

GLOBAL TRENDS IN CVD BURDEN

Understanding the Scope to Devise Solutions



The number of people dying from cardiovascular disease (CVD) is steadily rising, encompassing one-third of all deaths globally in 2019, according to a landmark paper published last month in the *Journal of the American College of Cardiology (JACC)*.

The paper, which uses data from The Global Burden of Diseases, Injuries, and Risk Factors Study 2019 (GBD 2019), reviews the total magnitude of CVD burden and trends over 30 years around the world and highlights 13 underlying causes of cardiovascular death and nine related risk factors. It also underscores the urgent need for countries to establish cost-effective public health programs aimed at reducing cardiovascular risk through modifiable behaviors.

This issue of *Cardiology* offers a closer look at the key findings from the paper and the opportunities for cardiovascular professionals around the world to use the data and knowledge to optimize patient care and outcomes and truly transform global health. Don't miss Number Check on page 6 for more insights from the GBD 2019.

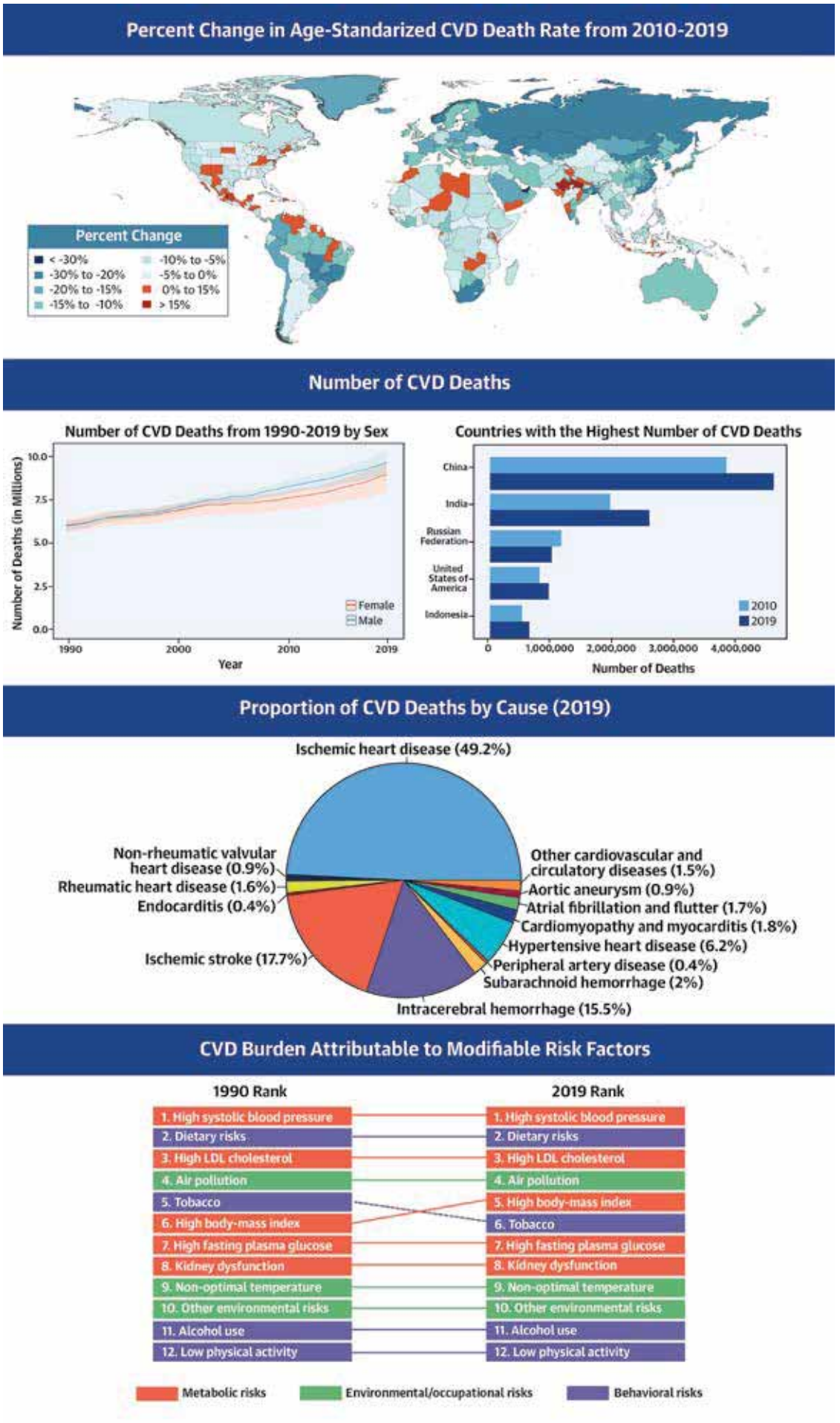
Table Cardiovascular Disease Insights From the GBD 2019 Study

Observation	Implication
The burden of CVD, measured in number of DALYs, continues to increase globally.	Population growth and population aging will require countries and health systems to prioritize the prevention and care of CVD.
A rise in the age-standardized rates of CVD DALYs over the past 5 yrs is a concerning trend seen in several subnational locations, including parts of the United States, Mexico, and the United Kingdom.	Subpopulations within countries are experiencing adverse trends in cardiovascular health, suggesting a need to support the delivery of interventions in high-risk locations.
Globally in 2019, CVD was the underlying cause of >6 million deaths occurring between the ages of 30 and 70 yrs.	CVD is a common cause of premature death among young and middle-aged adults, with 1.2 million CVD deaths in 2019 occurring in those younger than the age of 50 yrs.
The majority of global CVD burden is attributable to modifiable risk factors.	Inadequate risk factor control is an enormous global problem that demands innovative public health solutions.

CVD, cardiovascular disease; DALYs, disability-adjusted life years; GBD, Global Burden of Diseases, Injuries, and Risk Factors.
Roth GA, Mensah GA, Fuster V. J Am Coll Cardiol 2020;76:2980-1.

Scan the QR code to read the full paper in *JACC*.

Central Illustration: Cardiovascular Disease Burden Across Time, Location, Cause and Risk Factor



Roth, G.A. et al. J Am Coll Cardiol. 2020;76(25):2982-3021.

Global CVD Health and COVID-19

Amid the current COVID-19 pandemic, there exists high rates of excess mortality. According to the paper in *JACC*, much of this additional disease burden may be related to CVD, because of the effects of both viral infection and changes in the delivery of health care and health-seeking behaviors due to pandemic mitigation efforts.

In an Executive Summary accompanying the landmark paper, **Gregory A. Roth, MD, MPH, FACC; George A. Mensah, MD, FACC**; and **Valentin Fuster, MD, PhD, MACC**, note that the COVID-19 pandemic and related "large economic setbacks will require renewed commitments to meet Sustainable Development Goal 3, which seeks a 30% reduction in premature mortality due to noncommunicable disease by 2030." They note that "early studies suggest that direct and indirect excess cardiovascular mortality due to the coronavirus disease 2019 pandemic may be large, further stretching already limited investments in global cardiovascular health" and stress the importance of additional research, as well as continued global action.

"In the face of a global viral pandemic, we still must emphasize global commitments to reduce the suffering and premature death caused by CVD, which limits healthy and sustainable development for every country in the world," said Fuster.

> **"In the face of a global viral pandemic, we still must emphasize global commitments to reduce the suffering and premature death caused by CVD, which limits healthy and sustainable development for every country in the world."**
>
> **– Valentin Fuster, MD, PhD, MACC**

Get out your earbuds and listen to *JACC* Editor-In-Chief **Valentin Fuster, MD, PhD, MACC**, discuss highlights from the paper in a special podcast.

Global Health: What to Watch

In addition to highlighting global trends in CVD, the Global Burden of Disease paper offers insights into potential actions as well as opportunities going forward to turn the tide on CVD mortality. On the watch list:

- **Population growth and aging** are likely to increase the total prevalent cases of CVD worldwide, according to the study. In particular, countries in Northern Africa, Latin America and all of Asia are expected to be hardest hit. "Effective and affordable clinical strategies remain overlooked by health systems as targets for investments, including methods for noninvasive screening, use of combination pharmacotherapy medications to lower blood pressure and unhealthy cholesterol levels, investment in ambulance services and emergency care including for cardiac arrest, interventional structural and cardiac surgical services including for congenital and rheumatic heart disease, and wider access to rehabilitation services," the authors write.

> **"There is often a gap between the identification of a problem, the location of a solution and the translation of that solution to an entire population."**
>
> **– Gregory A. Roth, MD, MPH, FACC; George A. Mensah, MD, FACC; Valentin Fuster, MD, PhD, MACC, et al.**

- **Polypills** continue to be viewed as a possible solution to help control elevated blood pressure and related conditions, particularly in lower-income countries. Most recently, findings from the TIPS-3 study presented at AHA 2020 found the polypill reduced CVD by approximately 20% compared with placebo in people considered at intermediate risk for heart disease. Patients taking both a polypill plus aspirin saw even greater reductions. According to **Salim Yusuf, MD, BS, DPhil, FACC**, one of the authors of the TIPS-3 study, use of a polypill plus aspirin could prevent 3-5 million cardiovascular deaths globally and "future polypills, with newer statins, may reduce LDL cholesterol and blood pressure to a greater extent and could reduce cardiovascular disease risk greater than 50%." **Scan the QR code to read more on the study.**
- The prevalence of **Rheumatic Heart Disease** has been steadily increasing over the last 30 years, reaching 40.5 million in 2019, according to the paper. The authors note that an effective group A streptococcal vaccine could greatly decrease the burden of this disease, especially in low- to middle-income countries. In the meantime, the new ACC/AHA Guideline for Valvular Heart Disease includes recommendations for treating patients with rheumatic fever or evidence of rheumatic heart disease. **Scan the QR code to read more about the recommendations.**
- **Peripheral artery disease (PAD)** remains highly prevalent, increasing two-fold between 1990 and 2019. The paper notes that "the burden of PAD is increasing not only in developed [high-income countries] HICs but also in [low- and middle-income countries] LMICs, where concomitant risk factors such as diabetes and obesity are increasing." The authors call for greater regulation and further studies to help prevent and treat this disease.

About the Global Burden of Diseases, Injuries, and Risk Factors Study

A multinational collaborative research effort, the Global Burden of Diseases, Injuries, and Risk Factors Study estimates the burden of disease for every country worldwide. Updated annually, the study provides for consistent comparisons from 1990 to 2019, by age and sex and across locations. New diseases, new data sources and updated methods are included in the annual updates.

Standard epidemiological measures, such as incidence, prevalence and death rates, along with summary measures of health, such as disability-adjusted life-years (DALYs), are provided by the study. DALYs, the years of life lost prematurely and years lived with disability, are estimated using life tables, estimates of prevalence and disability weights.

Air Pollution: A Modifiable Risk Factor

Data from the GBD 2019 reinforce the impact of air pollution on health outcomes, including CVD. Learn more about this impact in a recent review article in the *Journal of the American College of Cardiology*. **Scan the QR code to start reading about this CV risk factor.**

What Cardiologists Can Bring to Global Health

How can cardiovascular professionals contribute to promoting advances in cardiovascular care at an individual and population level around the world? **Michel Ibrahim, MD**, a Fellow in Training at Boston University Medical Center, shares his insights on pursuing an advanced heart failure and transplant fellowship while also contributing to advancing cardiovascular care in his home country of Haiti. **Scan the QR code to read more and be inspired.**

TOP 10 TAKEAWAYS ON CVD AND RISK FACTORS FROM GBD 2019

By Ragavendra R. Baliga, MBBS, FACC

01. **CVD AND DISABILITY** Prevalent cases of total CVD nearly doubled from 271 million in 1990 to 523 million in 2019. The number of CVD deaths steadily increased from 12.1 million in 1990, reaching 18.6 million in 2019. The global trends for disability-adjusted life-years (DALYs) and years of life lost (YLLs) also increased significantly, and years lived with disability (YLDs) doubled from 17.7 million to 34.4 million over that period.

02. **ISCHEMIC HEART DISEASE (IHD)** The total number of DALYs due to IHD has risen steadily since 1990, reaching 182 million DALYs and 9.14 million deaths in the year 2019. This new report estimated 197 million prevalent cases of IHD in 2019.

03. **STROKES** The total number of prevalent strokes, deaths and DALYs due to stroke increased steadily from 1990, reaching 101 million prevalent stroke survivors (85.3% increase); 6.55 million deaths from stroke (43.3% increase); and 143 million DALYs due to stroke (32.4% increase) in 2019, with the bulk of the burden outside of the high-income world. Of 12.2 million incident stroke cases, 7.63 million (62.4%) were ischemic stroke, 3.41 (27.9%) were intracerebral hemorrhages, and 1.18 million (9.7%) were subarachnoid hemorrhages.

04. **Hypertensive Heart Disease** The global prevalence of hypertensive heart disease has risen steadily over the last three decades, as have the total number of deaths, DALYs, YLLs and YLDs due to this disease. In 2019, hypertensive heart disease was the main cause of 1.16 million deaths and 21.5 million DALYs annually, with a global prevalence of 18.6 million cases.

05. **CONGENITAL HEART DISEASE** A total of 3.12 million babies were born with congenital heart anomalies in 2019 representing 2,305.2 per 100,000 live births. A total of 13.3 million people were living with congenital heart anomalies, and this was the underlying cause of 217,000 deaths, of which 150,000 deaths were in infants younger than 1 year.

06. **RHEUMATIC HEART DISEASE** Rheumatic heart disease burden is highest among the world's disadvantaged populations. Its prevalence has been rising steadily since 1990, reaching 40.5 million currently affected in 2019. Deaths decreased until 2012 and then stabilized but have started increasing since 2017 (306,000 in 2019).

07. **CARDIOMYOPATHY AND MYOCARDITIS** The prevalence and related mortality of cardiomyopathy and myocarditis increase throughout adulthood in both sexes with a larger proportion of cases in men than in women. The increased prevalence associated with aging is more pronounced in cardiomyopathies than in myocarditis. DALYs due to cardiomyopathy and myocarditis have increased from 7.06 million to 9.14 million over the past 30 years, a pattern that is also seen in the rise of deaths from 238,000 to 340,000.

08. **ALCOHOLIC CARDIOMYOPATHY** Women are generally considered more susceptible to alcohol-induced damage than men, which may reflect sex-specific differences in alcohol consumption, type, blood level, distribution or metabolism. However, the higher level of alcohol consumption and the higher frequency of alcohol problems among men could justify the observed higher rate of DALYs. The global prevalence of alcoholic cardiomyopathy estimated by the 2019 report was 708,000 cases, approximately 9.1 cases per 100,000. Globally, alcoholic cardiomyopathy was responsible for 71,700 deaths, 2.38 million YLLs, and 60,100 YLDs.

09. **ATRIAL FIBRILLATION AND ATRIAL FLUTTER (AFIB/AFL)** The total number of DALYs due to AFib/AFL increased progressively from 3.79 million in 1990 to 8.39 million) in 2019. This new report estimated 59.7 million prevalent cases of AFib/AFL in 2019, about a doubling compared to the prevalent cases in 1990. Health systems and countries will need to focus their efforts to reverse these trends by aggressive attention to the reduction of risk factors such as hypertension, diabetes, and obesity; better treatment of individuals with IHD and heart failure; and improved access to medications for thromboembolism prophylaxis.

10. **AORTIC ANEURYSM** The total number of YLLs due to aortic aneurysm, including both thoracic and abdominal types, has increased steadily since 1990, reaching 3.32 million YLLs and 172,000 deaths in 2019.

Scan the QR code to read the full Key Points to Remember from the GBD 2019 paper in *JACC*.

Where Are They Now: Conversations With the 2020 ACC/Merck Fellowship Awardees

For the last four decades, the ACC and Merck have partnered together to provide research fellowships to nearly 200 cardiovascular clinicians in the early stages of their careers. These fellowships have stimulated and encouraged young scientists to pursue careers in research – many of whom have gone on to play leading roles in both their institutions and the ACC.

Cardiology recently caught up with the 2020 ACC/Merck awardees – **Darae Ko, MD, MSc**, and **Priya M. Freaney, MD** – to talk about their research, highlights to date, next steps and advice to other Fellows in Training and Early Career clinicians. Read their interviews below and see the sidebar for more information on the 2021 Merck Fellowships (the application deadline is Jan. 29) and save the date for ACC.21 in May where the newest awardees will be celebrated as part of Convocation.

Darae Ko, MD, MSc

Assistant Professor in Medicine
Boston University

Research and Highlights to Date:

My research project has focused on risk-guided atrial fibrillation (AFib) surveillance in ischemic stroke with the goal of establishing current national practice patterns in the use of an implantable loop recorder (ILR) after ischemic stroke for AFib surveillance.

I hypothesize that the practice patterns are highly variable, and this variability is mostly driven by patients' insurance status, physician subspecialty, and hospital characteristics rather than patient comorbidities. The findings from the project will benchmark post-stroke ILR use and estimate the magnitude of the potential opportunity to optimize ILR use for post stroke AFib detection.

Since the start of the ACC/Merck fellowship in July 2020, I published a paper as a second co-author in the journal *Stroke* investigating the feasibility of using data from electronic health records to phenotype cardioembolic stroke. Perhaps the most exciting news is that I found out recently my NHLBI K23 application received a fundable score.

Key Takeaways From the ACC/Merck Fellowship Experience

The biggest challenge for me during the fellowship was learning how to transition from fellow to faculty. There was a lot of grant writing to secure a faculty position with protected research time. The most important takeaway from this arduous experience is that as an early-career investigator, I could not have done my research without my mentors who believed in me and who wanted to help me. **Emelia J. Benjamin, MD, ScM, FACC**, (cardiology, Boston University), **Allan Walkey, MD, MSc**, (pulmonary and critical care, Boston University), and **Steven Lubitz, MD, MPH**, (cardiology, Harvard Medical School) are my closest mentors who consider it their mission to support the next generation of scientists.

Next Steps and Advice For the Future

I will transition to my K23 award after the ACC/Merck Fellowship ends. The K23 award will allow me to further develop research expertise in AFib and anticoagulation and become an independent researcher. My ultimate goal is to become an R01-funded investigator with a focus on identifying opportunities to improve health care delivery for AFib detection and treatment and developing effective strategies to prevent AFib-related complications.

I cannot emphasize enough the importance having a team of mentors. Mentors can make (or break) the careers of early-stage researchers. If you surround yourself with people who believe in you and want to support you, and you work hard, you will maximize your chance of successfully transitioning to the next stage of your career.

WILL YOU BE NEXT?

The ACC is excited to celebrate the 40th Anniversary of its partnership with Merck. In recognition of this milestone anniversary, ACC and Merck are offering three one-year fellowships totaling $100,000 each. One of the fellowships will be awarded by the Association of Black Cardiologists (ABC) to a current ABC member pursuing research focusing on disparities of care. Preference for all three awards will be given to individuals who have had no more than two years of prior full-time experience either in clinical or basic research. Recipients will be expected to pursue a full-time project in clinical research during their year of supported training, beginning July 1, 2021 and ending June 30, 2022. Awardees will be recognized during Convocation at ACC.21 in May.

ACC.21

NEW DATES!
ATLANTA
May 15 – 17

All applications must be complete and submitted by Jan. 29. Scan the QR code for more information on eligibility, selection criteria and the submission process.

Priya M. Freaney, MD

Cardiology Fellow
Northwestern University

Research and Highlights to Date

The overarching goal of my research is to better understand the role of adverse pregnancy outcomes in the future development of cardiovascular disease (CVD). Adverse pregnancy outcomes include hypertensive disorders of pregnancy, low birthweight of babies, and preterm delivery. Specifically, we aim to understand the association between adverse pregnancy outcomes and subclinical CVD to be able to implement strategies to prevent overt CVD.

In addition to presenting our work demonstrating the association of pregnancies complicated by low birthweight deliveries with adverse maternal heart health (cardiac mechanics) at ACC.20/WCC, I also presented our work on trends and disparities in adverse pregnancy outcomes at the Northwestern Cardiology Young Investigator Forum national conference and received the 3rd place clinical fellow award. I have also co-authored several manuscripts in *JAMA, Circulation: Heart Failure, American Journal of Medicine*, and *Current Atherosclerosis Reports* in the past year.

Key Takeaways From the ACC/Merck Fellowship Experience

The COVID-19 pandemic has certainly introduced challenges during my ACC/Merck fellowship year. As with many other researchers around the world, in-person participant recruitment, data collection and networking opportunities are currently compromised. Luckily, remote research and virtual connections have helped to fill this gap, though we eagerly await the safe return to in-person collaborations in the near future.

In all, however, the ACC/Merck fellowship has been a phenomenal opportunity. It has been incredibly valuable to have a full year of protected research time during my cardiology fellowship to dedicate to advancing my clinical research career. One simple but important message is that high-quality research takes time. I am so grateful to have the opportunity to receive dedicated training at Northwestern University Feinberg School of Medicine in the Department of Preventive Medicine to develop a strong foundation for a future career as a clinician scientist with the support of the ACC/Merck fellowship.

Next Steps and Advice For the Future

Following my ACC/Merck fellowship year, I plan to continue my research in women's cardiovascular disease prevention, obtain additional training in cardiovascular imaging, and ultimately aim to join or start a Women's Heart Health Center. My goal is to have both clinical and research programs that identify barriers to transitions of care from peripartum obstetric care to postpartum cardiovascular care, screening pathways for premature CVD, and related mechanisms for novel therapeutic targets to improve cardiovascular outcomes in women who have experienced adverse pregnancy outcomes.

I strongly advise any cardiology fellow who is pursuing a career in clinical investigation to apply for the ACC/Merck fellowship. The process of putting together the application alone serves as an opportunity to articulate your vision for a research proposal, and the prestigious fellowship can then launch your career as an early investigator and serve as a bridge to independent funding.

CONVERSATION WITH THE EXPERT

The COVID-19 Pandemic Has Changed Cardiac Telemedicine and Patient Monitoring, But What Will Happen Post-Pandemic?

COVID-19 has greatly impacted the health system since early 2020. In March, many states enacted stay-at-home orders. Many hospitals and health systems temporarily halted elective medical procedures in an effort to mitigate the risk of COVID-19 transmission; preserve personal protective equipment, hospital bed capacity, and equipment; and allow shifts in healthcare staffing patterns.[1]

During this time, the use of telemedicine vastly increased. During the first quarter of 2020, the number of telemedicine visits increased by 50% compared to the same period in 2019, with a 154% increase in visits observed in the last week of March 2020 compared to the same period in 2019.[2] As a result, the Centers for Medicare & Medicaid Services enacted emergency policies related to telemedicine that, among other changes, allowed virtual visits to be conducted from patients' homes rather than in a healthcare setting.[2,3]

Patients with cardiac conditions are at an increased risk for COVID-19-related morbidity and mortality. Emergency department admissions for heart failure and heart attacks have notably decreased, which may be due to patient reluctance to visit healthcare facilities during the pandemic.[4]

Remote patient monitoring cardiac devices offer a safe solution to telemedicine during the pandemic.[4] The Zio XT monitor is a prescription-only, single-patient-use, continuously recording electrocardiogram monitor that can be worn up to 14 days. It is indicated for use on patients who may be asymptomatic or may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, presyncope, syncope, fatigue, or anxiety.[5]

In response to the pandemic, iRhythm expanded its home enrollment for its Zio single-use cardiac monitors, shipping the devices directly to patients' homes for application and use.[6] This home enrollment option reduces potential patient and staff COVID-19 exposure by eliminating office visits, removes the need for cleaning or reusing returned monitors that may have been exposed to the virus, and ensures patients continue to receive access to cardiac care during the pandemic.[7]

Clinical discussion with:

Andre Gauri, MD, FHRS
Cardiologist and Electrophysiologist
Spectrum Health

Clinical Insights

Andre Gauri, MD, FHRS, a cardiologist and electrophysiologist at Spectrum Health in Michigan, discussed how COVID-19 has impacted cardiac care, the role of home monitoring and telemedicine, and the healthcare changes that are still ahead.

How have the surges in COVID-19 infections affected your patients, patient volume, and practice?

When COVID-19 hit the United States, we at Spectrum Health went into partial shutdown mode and limited care to only emergent cases.

We saw what was happening in New York and Detroit where the healthcare system was extremely overwhelmed. Although we had many COVID-19 patients in the spring, we never really overwhelmed our system. Patients were scared to come to the hospital, so many people were deferring care. We quickly realized, in a matter of a few weeks, that we could and needed to safely take care of patients who were not dealing with COVID-19. We had the bandwidth to open our doors again to do more elective and semi-elective procedures. Although we observed a major dip in elective care initially, by mid-May 2020 we were able to successfully ramp up to normal volumes.

When COVID-19 surges occurred again in the fall of 2020, the system was much more prepared given the experiences and lesson learned from earlier in the year. On the cardiac side, very few cases were postponed even though we had almost three to four times as many COVID-19 patients in the hospital compared to the spring. The fact that much of the cardiac care was same-day discharge and not requiring a hospital bed allowed us to care for patients despite a high hospital census.

Can you discuss your process for implementing telemedicine? Were there any challenges?

When the pandemic first hit and most medical groups went into a shutdown, we were only seeing emergent patients in person. Almost everyone was at home seeing patients virtually. On my team of eight electrophysiologists, we had one person assigned to the hospital, one to the office, and the rest were seeing patients virtually.

There's a famous saying, "Don't let a tragedy go to waste," and the pandemic really made providers quickly focus on developing alternatives to care for our patients. We went from seeing a very limited number of patients through telemedicine—approximately 5% of patients mainly in rural areas—to seeing 80% of our patients via telemedicine in a matter of days to weeks. *[Learn more by watching Dr. Gauri share how he and his team maintained continuity of care amid the COVID-19 pandemic at irhythmtech.com/acc.]*

Our existing telemedicine platform wasn't built for that volume, and technical issues surfaced at first. Patients didn't have the right software, didn't have good Wi-Fi, and had difficulties connecting. In talking to colleagues across the country, many people struggled with this as well.

Cardiac electrocardiogram monitoring technologies like Zio by iRhythm also allowed us to mitigate patient concerns about coming to the hospital. Because Zio allows for home enrollment of monitors and sends a comprehensive report at the end of the 14-day patient wear period, we were able to eliminate the need for patients to travel. Zio was instrumental in helping Spectrum make the transition to remote care and telehealth easier. I was really proud of our leadership team coming together, stepping up, and allowing the changes in telehealth to take place that provided continued patient care.

How have you or your team thought through the different monitoring modalities available as you think about adapting to COVID-19?

As an electrophysiologist heart rhythm specialist, many of our patients require monitoring. When COVID-19 started, only urgent patients were coming in the clinic. As we moved to telemedicine, we questioned how we were going to care for patients remotely if we saw they were having symptoms that warranted a cardiac monitor. The Zio monitor really helped us continue to care for and monitor our patients without them ever leaving their homes. That was a tremendous benefit to the arrhythmia patients, driving 98% patient compliance, which in turn provided us with more accurate data.[8]

Another advantage of using these single-use Zio patches is that concerns of transmissible diseases were essentially eliminated. Reuseable Holter monitors require additional cleaning and sterilization due to COVID-19 concerns and possible risk of transmission to both staff and patients.

With COVID-19, have you seen any new patient types?

Researchers are seeing more patients with cardiovascular symptoms stemming from COVID-19, ranging from chest pain to palpitations to presyncope or syncope as well as myocarditis. These are just some of the symptoms that COVID-19 "long-haulers" experience. We anticipate a whole new heart patient population from this group in the future.

Are you seeing a decline in cardiac health in patients delaying care?
Absolutely. In the electrophysiology space, patients who develop atrial fibrillation that is poorly controlled can develop a weakened heart muscle that is related to their atrial fibrillation, known as a tachycardia-induced cardiomyopathy. Patients were having symptoms and not seeking medical attention in the appropriate time frame, coming in with later rather than early presentations of cardiac diseases. When they finally came in due to significant difficulty breathing or walking, they had already developed congestive heart failure.

Delayed presentations also occurred with heart attacks and strokes. A complication from a late presentation of myocardial infarction could be a ruptured papillary muscle, or ventriculoseptal defect, but we rarely see those because most people who have a heart attack present early and get revascularized immediately. We were seeing a tremendous increase in these rare cases because patients weren't coming in for medical attention and not getting revascularized.

These patients are the secondary COVID-19 casualties: They didn't have a problem directly related to COVID-19, but they did develop significant morbidity as a result of not seeking medical attention during the pandemic. Because Zio can be applied at home by the patients themselves, cardiac monitoring does not have to be deferred. Patients will have clinically better outcomes with earlier treatment.

In recent clinical studies, Zio was able to detect atrial fibrillation in moderate-risk patients earlier, supporting the prevention of serious cardiac events after diagnosis. Active monitoring with Zio also led to fewer hospitalizations for bleeding and fewer total hospitalizations.[9]

Active, early monitoring with Zio can help patients stay home and out of the hospital.

What are patients' sentiment now in resuming care?
Fortunately, patients are feeling more comfortable as we learn more about the virus—knowing that if you're safe, wear a mask, and wash your hands, you can still leave your house. We did a lot of public service messaging around continuing to see your doctor if you're having problems. We tried to educate patients that if they're having acute medical issues, they should not delay care. I think that was very helpful in making patients feel more comfortable seeking medical attention.

Still, as we return to in-person care, there are a number of cases that are better suited for remote monitoring; not all cases involve acute medical issues. Our augmentation of telemedicine has freed the in-person resources for the most critical cases.

Where do you foresee the role of cardiac monitoring going in 2021? What patient behavior changes do you anticipate post-COVID-19?
Cardiac monitoring with iRhythm's home enrollment has been very helpful. If I'm seeing a patient who lives many miles from our office, I'm now seeing that patient via telehealth. Instead of having to come to get a monitor placed in person, we can do home delivery and home enrollment with Zio. We have developed a system where we can more broadly expand telehealth solutions to patients long-term, not just during the pandemic. There's clear benefit to both the patient and the system here.

Will telehealth increase in popularity or revert to pre-COVID-19 levels?
At our peak, we were seeing probably 70% to 80% of our patients via telehealth. We've learned that many patients would rather see a provider in person if given the choice. The doctor-patient relationship is extremely important yet somewhat diminished via telehealth. Obviously, not being seen at all is worse than being seen over a computer, but I definitely think there's a fine balance.

At the end of the day, there are many people who just want to leave the house and see their doctor in person. I think we will find a balance where maybe 20% to 25% of patients will be seen via telehealth, and the rest would still be seen in person—time will ultimately tell.

For 2021, the American Medical Association released new Current Procedural Terminology (CPT) codes that address longer-term cardiac monitoring. Will this change the way you care for patients?
We have been long-term users and early adopters of long-term cardiac monitoring with iRhythm's Zio monitor. For the first several years, this was a real struggle mainly because of insurers not covering the test because it didn't have a CPT code. Often, patients would get stuck with bills or have to do a lot of backend work to settle their bill in an agreeable fashion. This really is amazing technology that we've been using for almost 10 years now, and I'm so grateful that this payment barrier is finally gone.

I have used many devices over the years, including other mobile cardiac outpatient telemetry systems and patch-type extended Holters. In terms of insurance coverage, it's the type of device that poses potential coverage concerns not the specific device brand. The biggest advantage of the iRhythm products is the format of their device reports. They are structured in an intuitive and concise fashion with clinically relevant information readily available. This significantly reduces the time it takes [me] to interpret a report and make necessary clinical patient care decisions.

Every single atrial fibrillation patient I treat usually has several monitors over the course of their care—pre-ablation, post-ablation, and follow-up. I'm not necessarily going to order more monitors now, but I think it's going to be a lot easier for patients since they are not going to face insurance payment barriers.

What long-term changes do you see taking effect? How do you see the pandemic shaping cardiac care?
From a regulatory and technology standpoint, I see change occurring at a much faster pace. Some of the regulatory restrictions on telemedicine hopefully will no longer exist. There has been a huge boon for third parties developing telehealth technologies that are more patient- and healthcare system-friendly. Many of our patients are elderly and are not very technologically savvy, so you have to make it very easy for them to use. These technologies will allow more real-time health data to be shared with providers and hopefully allow for earlier detection of disease and better management of chronic illnesses such as heart failure and diabetes.

Dr. Gauri is a board-certified cardiologist and electrophysiologist and is a Fellow of the Heart Rhythm Society. He is the chief of cardiac electrophysiology and medical director of the Atrial Fibrillation Program at Spectrum Health in Grand Rapids, Michigan. He is a clinical assistant professor of medicine at Michigan State University, College of Human Medicine. Dr. Gauri earned his medical degree from Stritch School of Medicine, Loyola University in Maywood, Illinois, and completed his internal medicine residency at Stanford University School of Medicine in Stanford, California. He completed his cardiology fellowship at University of Chicago and completed his electrophysiology cardiology fellowship at Loyola University Medical Center in Maywood, Illinois. Dr. Gauri's clinical interests include catheter ablation of atrial fibrillation and other complex arrhythmias and implantation of pacemakers, cardiac defibrillators, and resynchronization devices.

Dr. Gauri received compensation for his contribution to this initiative.

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Making News in 2020

Without a doubt, the top news of 2020 was the COVID-19 pandemic. From the beginning, ACC was at the forefront of generating clinical guidance, providing expert commentary and facilitating the sharing of new research and front-line perspectives.

Top articles in 2020 include *Cardiology* magazine features on the risk of infectious agents and an exclusive interview with **Anthony S. Fauci, MD;** ACC's guide to safely resuming cardiovascular procedures, diagnostics and tests; insights from clinicians on the front lines of treating patients in China; and more. ACC's COVID-19 Hub includes links to these articles and much more.

Important cardiovascular research didn't stop with the pandemic. Hot clinical trials like VOYAGER-PAD, RIVER, and more made headlines from major cardiovascular meetings, including ACC.20/WCC Virtual. Additionally, ACC's new expert consensus decision pathway on novel therapies for cardiovascular risk reduction in patients with type 2 diabetes, as well as new ACC/American Heart Association (AHA) guidelines addressing hypertrophic cardiomyopathy and valvular heart disease were also released in 2020.

Other top articles include a *Cardiology* magazine cover story addressing implicit bias; a joint statement from the ACC, the Association of Black Cardiologists and the AHA addressing issues of racism and violence; and a landmark *JACC* state-of-the-art review looking at the global burden of cardiovascular disease over the last 30 years (read more on this in our cover story on page 20).

Scan the QR code for the complete list and read the top 10 articles from 2020.

***JACC* and Family:** Most Talked About Articles in 2020

Hundreds of articles are published every year across all eight – and soon to be nine – of the journals in the *JACC Family of Journals.*

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1. **Saturated Fats and Health: A Reassessment and Proposal for Food-Based Recommendations: *JACC* State-of-the-Art Review**
2. **Training for a First-Time Marathon Reverses Age-Related Aortic Stiffening**
3. **Reduction in ST-Segment Elevation Cardiac Catheterization Laboratory Activations in the United States During COVID-19 Pandemic**
4. **Association of Treatment Dose Anticoagulation With In-Hospital Survival Among Hospitalized Patients With COVID-19**
5. **COVID-19 and Thrombotic or Thromboembolic Disease: Implications for Prevention, Antithrombotic Therapy, and Follow-Up: *JACC* State-of-the-Art Review**

Visit *JACC.org/MostTalkedAbout* for a list linked to the top five most talked about articles from each of the *JACC* specialty journals: *JACC: Clinical Electrophysiology; JACC: Heart Failure; JACC: Cardiovascular Imaging; JACC: Cardiovascular Interventions; JACC: Basic to Translational Science; JACC: Case Reports and JACC: CardioOncology.*

Pop Quiz!

What are TICO, EMPEROR-Reduced, VICTORIA, RIVER, EAST-AFNET 4, VERTIS CV, RATE-AF, REALITY, POPular TAVI and LoDoCo2? Answer: The Top Clinical Trials on *ACC.org* in 2020.

Scan the QR code to read the trial summaries and keep current, and read the Top 10 Journal Scans, all from the *ACC.org* Editorial Team.

Late-Mortality Signal Associated With Paclitaxel-Coated Devices: An Update

In December 2018, Katsanos, et al., surprised the vascular community in publishing a meta-analysis demonstrating a late mortality signal for patients treated with paclitaxel-coated devices (PCDs) relative to uncoated devices.[1] Specifically, they performed a meta-analysis of summary-level data from randomized-controlled trials (RCTs) that showed an increase in mortality at two and five years (68% and 93% increase in risk, respectively) in patients treated with PCDs relative to uncoated percutaneous transluminal angioplasty (PTA) and bare metal stenting (BMS) in the femoropopliteal artery segment.

This meta-analysis has several methodological flaws for which it has been criticized. For example, the individual RCTs included in the study were designed to evaluate short-term safety endpoints. Therefore, there was significant loss to follow-up after the specified short-term endpoints were met. This is evident in the meta-analysis as the one-year analysis included 28 trials and 4,432 patients, whereas the five-year analysis included only three trials and 863 patients. The patient populations in the individual RCTs were also heterogeneous in terms of their comorbidities and lesion characteristics as well as the endovascular devices used. Because individual-level data were not analyzed, these differences in patient populations were not accounted for and may have biased the results of the meta-analysis.

Despite its flaws, the consequences of the Katsanos meta-analysis were far-reaching. RCTs, including BASIL III and SWEDEPAD I and II, were stopped.[2] The U.S. Food and Drug Administration (FDA) recommended that health care providers restrict the use of PCDs to high-risk patient populations.[3] Prior to the publication of the Katsanos meta-analysis, PCDs had emerged as the standard of care for patients undergoing endovascular revascularization because they increase primary patency rates and reduce target-lesion revascularization relative to PTA and BMS.[4-6]

The FDA convened a Medical Device Advisory Panel in June 2019 to investigate the possibility of a late mortality signal associated with PCDs. In preparation, the FDA had analyzed internal pivotal trial data of FDA-approved PCDs, which included several trials that had been analyzed in the Katsanos meta-analysis. In their analysis, the FDA identified a late mortality signal associated with PCDs. However, they felt that no overarching conclusion could be drawn as there was substantial residual missing data, small patient sample sizes, and no clear relationship between paclitaxel dose and mortality.[7] The FDA also reviewed observational data from Medicare claims, Optum claims, and the Vascular Quality Initiative registry.[8] These analyses did not identify an association between PCDs and mortality.

The FDA concluded from the advisory panel that there was a signal of harm present, but a causal relationship could not yet be established. The FDA requested more long-term data to evaluate the possibility of a late mortality signal. They allowed these devices to remain on the market, but published a revised FDA Letter to Health Care Providers that reinforced the recommendations that PCDs should be reserved for patients at the highest risk of restenosis and alternative treatment options should be considered.[9]

New Data, More Insights

Since the FDA advisory panel, several studies have evaluated the association of mortality with paclitaxel. These include large observational studies, longer-term follow-up data from RCTs, and a meta-analysis of clinical trials (**Table 1**).

There have been multiple additional real-world observational data published, all of which have not demonstrated an increase in mortality among patients treated with PCDs compared with those treated with uncoated devices. These include studies performed in the Medicare database,[10,11] German BARMER insurance claims database,[12] data on the application of paclitaxel-based drug-eluting stents (DES)[13] and a study in the Society for Vascular Surgery Vascular Quality Initiative registry.[14]

The ongoing Safety Assessment of Femoropopliteal Endovascular treatment with Paclitaxel-coated Devices (SAFE-PAD) study (*clinicaltrials.gov* NCT04496544)[15] includes prespecified sensitivity analyses to assess the influence of unmeasured confounding as well as subgroup analyses to examine low-risk populations, inpatients vs. outpatients, critical limb ischemia (CLI), and device type among Medicare patients. The first report from this study has reaffirmed findings from previous Medicare analyses, with no evidence of long-term harm associated with these devices.

Rocha-Singh, et al., performed a meta-analysis of individual patient-level data from eight RCTs.[16] As part of this analysis, the investigators obtained follow-up data that reduced the loss to follow-up present in the original studies. With 27% and 25% loss to follow-up in treatment and control arms, respectively, they reported a mortality hazard ratio associated with PCDs of 1.38 (95% confidence interval [CI], 1.06-1.80). When loss to follow-up was reduced to 10% and 9% for treatment and control arms, respectively, the hazard ratio decreased to 1.27 (95% CI, 1.03-1.58). Hence, although the authors demonstrate a relationship between treatment with PCDs and mortality remained, they showed this association was attenuated as loss to follow-up was reduced. This suggests that patients missing long-term follow-up may not have been lost at random. Notably, there was no evidence of a dose-response relationship between paclitaxel and mortality.

Long-term follow-up from industry-sponsored RCTs also have been reassuring. This includes five-year data from IN.PACT SFA and IN.PACT Japan,[17] four-year results from the Illumenate Pivotal trial,[18] and five-year follow-up data from the LEVANT trials.[19] A five-year as-treated analysis from the Zilver PTX trial comparing 336 patients who were treated with DES to 143 patients treated with PTA showed no difference in mortality between the two groups.[20] For all these analyses, causes of death were analyzed between each treatment arm and no significant differences were identified.

An unplanned interim analysis from SWEDEPAD was recently published. The multicenter, randomized trial assigned 2,289 patients to either a drug-coated device or uncoated device and followed them a mean 2.49 years. No difference was seen in all-cause mortality between patients treated with PCDs (25.5%) vs. uncoated devices (24.6%) (HR, 1.06; 95% CI, 0.92-1.22). Stratification by CLI and intermittent claudication showed no difference in mortality between patients with CLI treated with PCDs vs. uncoated devices (HR, 1.04; 95% CI, 0.90-1.21). Similarly, no difference was seen in mortality in patients with intermittent claudication treated with PCDs vs. uncoated devices (HR, 1.18; 95% CI, 0.72-1.93).[25]

Hess, et al., performed a subgroup analysis of patients who underwent endovascular revascularization with PCDs or non-PCDs in patients from the VOYAGER PAD trial.[21] The VOYAGER PAD trial was a double-blind, placebo-controlled trial of patients with PAD undergoing lower-extremity revascularization who were randomized post treatment to receive rivaroxaban 2.5 mg bid or placebo on a background of aspirin 100 mg daily.[22] Of the 4,379 patients in the trial who underwent endovascular revascularization, 31% (1,358) were treated with a PCD. Patients were followed for a median of 31 months and vital status was ascertained for 99.6% of patients. After adjusting for confounders using inverse probability of treatment weighting, the investigators found no association between treatment with PCDs and mortality.

The Way Ahead?

In summary, since the publication of the Katsanos meta-analysis, there have been ample data published or presented from large, observational datasets, subgroup analyses from RCTs, and long-term follow-up from the pivotal PCD RCTs. None of these studies has been able to replicate an association between PCDs and mortality. Furthermore, several studies have now analyzed causes of death in patients who were treated with PCDs vs. non-PCDs and have not found significant differences between groups. Lastly, no clear mechanism relating paclitaxel to death has been described and a dose-response relationship between paclitaxel and mortality has not been established. As this controversy is now approaching two years, the vascular community awaits next steps from the FDA and other regulatory bodies in determining the long-term future of PCDs.

References available with the online version of this article at ACC.org/Cardiology.

Table 1 Key Studies Investigating Safety of PCDs vs. Non-PCDs.

	Key Studies of Mortality in PCDs	Time to Follow-Up	Mortality Difference
Observational Studies	Secemsky et al. JAMA 2019[10]	Median 389 days, up to 600 days	**No increase in mortality for PCDs** - unadjusted cumulative incidence through 600 days: 32.5% PCD vs. 34.3% non-PCD (p=0.007) - aHR, 0.97, 95% CI, 0.91-1.04 (p=0.43)
	Secemsky et al. JACC. 2019[11]	Median 2 years, up to 4.1 years	**No increase in mortality for PCDs** - unadjusted cumulative incidence through 4.1 years: 51.7% PES vs. 50.1% BMS (p=0.16) - aHR, 0.98; 95%CI, 0.93-1.03 (p=0.53)
	OPTUM Claims Data[18]	Median 2.66 years, up to 4.75 years	**No increase in mortality for PCDs** - aHR for mortality of PCDs vs. non-PCDs: 1.03, 95% CI, 0.96-1.10 (p=0.39)
	Freisinger et al. ESC 2019[12]	Median 92 months, up to 11 years	**No increase in mortality for PCDs** - HR at 5 years for PES vs. non-PCD: 1.01, 95% CI, 0.83-12.3 (p=0.91) - HR at 5 years for PCB vs. non-PCD: 0.97, 95% CI, 0.89-1.06 (p=0.492)
	Behrendt et al. Eur J Vasc Surg 2020[13]	5 years	**No increase in mortality for PCDs** - aHR for survival in PCD vs. non-PCD in patients with IC: 0.87, 95% CI, 0.76-0.99 - aHR for survival in PCD vs. non-PCD in patients with CLTI: 0.83, 95% CI, 0.77-0.90
	Bohme et al. JACC Cardiovasc Interv 2020[23]	Median 51 months	**No increase in mortality for PCDs** - Mortality rate 27.5% after PTA vs. 16.9% after PCB (p<0.001)
	Hess et al. TCT Connect 2020[21]	Median 31 months	**No increase in mortality for PCDs** - adjusted HR, 0.95, 95% CI, 0.83-1.09 (p=0.49)
Meta-Analysis	Rocha-Singh et al. Circulation 2020[16]	Median 4 years, up to 5 years	**PCDs conferred increased risk of mortality** - aHR for PCDs vs. non-PCDs with 27% and 25% loss to follow-up, respectively: 1.38, 95% CI, 1.06-1.8 - aHR for PCDs vs. non-PCDs with 10% and 9% loss to follow-up, respectively: 1.27, 95% CI, 1.03-1.58
Clinical Trials	Schneider et al. CCI 2020 (IN.PACT)[17]	5 years	**No increase in mortality for PCDs** - cumulative incidence of mortality for PCD 14.7 vs. 12.0 for PTA; HR, 1.39, 95% CI, 0.76-2.57 (log-rank p=0.286)
	Gray et al. Circulation 2019 and Lyden LBCT 2020 VIVA presentation (ILLUMENATE)[24,18]	4 years	**No Increase in Mortality for PCDs** - All-cause death for PCB 17.7% vs. 14.1% for PTA (p=0.494)
	Ouriel et al. JACC Cardiovasc Interv 2019 (LEVANT)[19]	5 years	**No increase in mortality for PCDs** - HR for survival for PCB vs. PTA: 1.01, 95% CI, 0.68-1.52 (p=0.95)
	Dake et al. 2020 (Cook Zilver PTX)[20]	5 years	**No increase in mortality for PCDs** - All-cause mortality for DES 19.1% vs. 17.1% for PTA/BMS (p=0.60)
	Nordanstig et al. (SWEDEPAD)[25]	Mean 2.49 years	**No Increase in Mortality for PCDs** - All-cause mortality for PCDs 25.5% vs. 24.6% for PTA/BMS (HR, 1.06; 95% CI, 0.92-1.22)

BMS, bare-metal stent; CI, confidence interval; CLTI, chronic limb-threatening ischemia; HR, hazard ratio; IC, intermittent claudication; PCB, paclitaxel-coated balloon; PES, paclitaxel-eluting stent; PTA, percutaneous transluminal angioplasty.

Blue highlight indicates studies that did not find an increase in mortality associated with PCDs and orange highlight indicates studies that found an association.

This article was authored by **Anna Katherine Krawisz, MD,** chief cardiology fellow at Beth Israel Deaconess Medical Center (BIDMC), and **Eric A. Secemsky MD, MSc, FACC,** director of Vascular Intervention in the CardioVascular Institute at BIDMC, and assistant professor at Harvard Medical School, and the Smith Center for Outcomes Research in Cardiology at BIDMC.

Reimagining the Heart Health Journey

Over the past year, the COVID-19 pandemic has further highlighted the challenges facing cardiovascular patients seeking to navigate the complex health care landscape. With no clear compass to guide their health journey, many patients are left trying to make sense of symptoms on their own and experiencing delays in diagnosis and/or treatment due to a health system that has reached critical mass.

How can we change this trajectory and make patients the architect of their own health care journey? One solution is a technology infrastructure that puts patients first and enhances their engagement with their clinicians and the health care system outside of clinic-based settings. Enter Evidation Health.

As part of its strategic Innovation efforts, the ACC is joining forces with Evidation Health to co-develop and launch Achievement for Heart Health, an individualized, curated health program. Co-developed by a team of experts from the ACC, Achievement for Hearth Health is designed to empower individuals to better manage their heart health from anywhere.

Through the program, which will initially focus on heart failure, individuals will be able to continuously monitor and learn from data relevant to their cardiovascular health from the comfort of their home. Individuals can share activity, sleep, blood pressure, and symptom information, including permissioned app and wearable data (**Figure 1**). Participants will also receive personalized, evidence-based educational content on topics like heart medications, nutrition, and stress management from ACC's CardioSmart program.

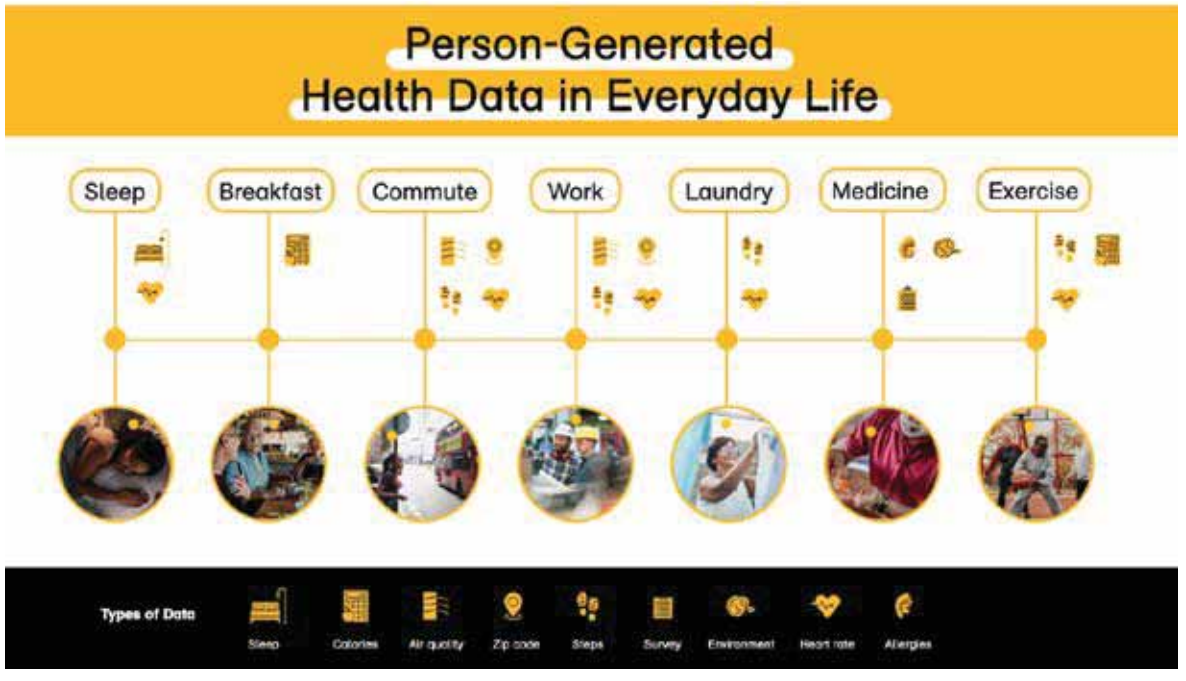
"The Achievement for Heart Health program will help the ACC and our research partners better understand the complex, individualized patient journey of those with heart failure, with a goal of improving how patients live with and manage one of the most common cardiovascular conditions affecting Americans today," said ACC Chief Innovation and Science and Quality Officer **John S. Rumsfeld, MD, PhD, FACC.** "The combination of Evidation's platform and ACC's clinical and scientific expertise will enable groundbreaking opportunities to transform cardiovascular care and improve heart health and outcomes."

The new program will be built on Evidation's Achievement platform and will be open to collaborators following Evidation's consent-per-use model, where participants provide consent for each program in which they participate and receive compensation for their contribution to research. The platform is the largest and most demographically and geographically diverse connected cohort in the U.S., representing

50 states and nine of every 10 ZIP codes nationwide. Learnings from this program will be used to iteratively inform and refine the patient experience, providing more tailored insight and support to navigate the health care system.

"We are proud to collaborate with the ACC, which is already leading the digital transformation of cardiovascular care delivery, to broadly expand individuals' access to their world class expertise, research, and educational resources," said **Deborah Kilpatrick, PhD,** Co-CEO of Evidation. "Together with the ACC, we look forward to collaborating with researchers and sponsors who are committed to developing products and services that are directly informed by patients in their everyday life."

Figure 1



Interested in Getting Involved?

The ACC and Evidation invite collaborators who share an interest in developing new ways to empower individuals to better manage their heart health to reach out at *partners@evidation.com*.

Scan the QR code to learn more about ACC's Innovation activities.

Implementing the New ACC/AHA Guideline on Valvular Heart Disease

An updated *Guideline for the Management of Patients With Valvular Heart Disease* (VHD) includes expanded treatment options, recommends fewer invasive interventions, when possible, and stresses the importance of patient involvement in treatment considerations.

The new guideline from the ACC and American Heart Association (AHA), and published in the *Journal of the American College of Cardiology,* replaces the 2014 guideline and a focused update from 2017, and includes an extensive review of available data through March 1, 2020.

Highlighted in the guideline is expansion of indications for transcatheter aortic valve implantation (TAVI) as a result of multiple randomized trials of TAVI vs. surgical aortic valve replacement. According to the guideline, "the choice of type of intervention for a patient with severe aortic stenosis should be a shared decision-making process that considers the lifetime risks and benefits associated with type of valve (mechanical vs. bioprosthetic) and type of approach (transcatheter vs. surgical)."

In addition, the evidence for non-vitamin K oral anticoagulants (NOACs) has improved since the last guideline was published, and the new guideline includes a class 1 level A recommendation that states: "For patients with AFib and native valve heart disease (except rheumatic mitral stenosis) or who received a bioprosthetic valve >3 months ago, a NOAC is an effective alternative to [vitamin K antagonist] VKA anticoagulation and should be administered on the basis of the patient's CHA_2DS_2-VASc score."

Other recommendations address the optimal timing of intervention for severe aortic stenosis, which depends on the severity of the valve condition, as well as the safety and long-term effectiveness of treatment options. The guideline authors note that the recommended timing of interventions will shift to earlier in the disease course for some patients as ongoing clinical research data evolves. Additionally, the guideline recommends that patients with severe VHD and who are being considered for valve repair or replacement should be evaluated by a specialized team working with a primary or comprehensive valve center.

> "Integration of this expanded evidence base, in conjunction with expert clinical experience, **will furnish both providers and patients with the guidance needed** to ensure optimal outcomes for patients with heart valve conditions." **Catherine Otto, MD, FACC**

Shared decision-making and the use of less-invasive treatment options are other important aspects of the new guideline. "Clinical studies have demonstrated the safety and effectiveness of new, less-invasive approaches for treatment of heart valve dysfunction," says **Catherine Otto, MD, FACC,** co-chair of the guideline writing committee. "Integration of this expanded evidence base, in conjunction with expert clinical experience, will furnish both providers and patients with the guidance needed to ensure optimal outcomes for patients with heart valve conditions."

Looking ahead, the guideline committee recommends more disease-specific studies and patient-centered trials that focus on each stage of the disease process. "While this guideline focuses on patients with end-stage heart valve disease, future research will also lead to treatments to prevent heart valve disease or earlier interventions to slow its progression," explains Otto.

"There is a knowledge explosion in medicine today, which can overwhelm the clinician," says **Rick A. Nishimura, MD, MACC,** co-chair of the writing committee. "This is particularly true in the area of VHD, in which multiple investigational trials are being rapidly performed and released, so that it becomes extremely difficult for an individual clinician to keep up with optimal treatments for each specific patient. The Valvular Heart Disease Guideline brings together experts in the field who review all the data and arrive at a consensus opinion for best treatment, outlined in the Class Recommendations."

The guideline was developed in collaboration with and endorsed by the American Association for Thoracic Surgery, the American Society of Echocardiography, the Society for Cardiovascular Angiography and Interventions, the Society of Cardiovascular Anesthesiologists and the Society of Thoracic Surgeons.

Putting the VHD Guideline Into Practice

Scan the QR code to visit the ACC's VHD Guideline Hub for the complete guideline, slides and other clinician and patient education resources, including the VHD Guideline Made Simple Tool and more.

Learn best through cases? Don't miss these from *JACC: Case Reports.*

Easily search within the guidelines from your desktop with ACC's new search tool at *ACC.org/Guidelines.*

Involve your patients in their VHD care using CardioSmart shared decision-making tools and focused infographics on VHD and TAVR. Learn more at *CardioSmart.org.*

KEY PERSPECTIVES:

VHD Guideline Key Points to Remember

David S. Bach, MD, FACC, *highlights general considerations for patients with aortic stenosis (AS), aortic regurgitation (AR) or bucuspid aortic valve (BAV).*

1 The guideline continues to recommend the use of disease stages among patients with VHD: Stage A (at risk), Stage B (progressive), Stage C (asymptomatic severe; with ventricular compensation [Stage C1] or with ventricular decompensation [Stage C2]), and Stage D (symptomatic severe). Disease stages should be assigned based on valve anatomy, the severity of valve dysfunction, the ventricular and pulmonary circulation response to valve dysfunction, and symptoms.

2 Among patients with atrial fibrillation (AFib) and native heart valve disease other than rheumatic mitral stenosis, or in patients with AFib and a bioprosthesis >3 months after valve replacement, a NOAC is an effective alternative to anticoagulation with a VKA; among these patients, either a NOAC or VKA should be used based on the CHA_2DS_2-VASc score. Anticoagulation with a VKA should be used in patients with AFib and rheumatic mitral stenosis. A NOAC should not be used in patients with a mechanical prosthesis without or with AFib.

3 All patients with severe VHD being considered for intervention should be evaluated by a Multidisciplinary Heart Valve Team. Consultation with or referral to a Primary Valve Center or a Comprehensive Valve Center is reasonable for the discussion of treatment options in the setting of asymptomatic patients with severe VHD, patients who might benefit from valve repair rather than valve replacement, and patients with multiple comorbidities.

4 In patients with severe symptomatic (Stage D) AS, the disease is subcategorized based on the gradient, flow and left ventricular ejection fraction (LVEF). Stage D1 reflects patients with high-gradient symptomatic AS (V_{max} ≥4.0 m/s, mean gradient ≥40 mm Hg, aortic valve area [AVA] ≤1.0 cm^2); Stage D2 reflects low-flow, low-gradient severe AS with reduced LVEF (AVA ≤1.0 cm2, V_{max} <4.0 m/s or mean gradient <40 mm Hg, LVEF <50%); and Stage D3 reflects low-flow, low-gradient severe AS with normal LVEF ("paradoxical low-flow severe AS"; LVEF ≥50%, stroke volume index <35 ml/m^2).

5 Intervention for severe AS predominantly is based on the presence of symptoms or LV systolic dysfunction (Class 1); or in asymptomatic patients at low surgical risk with decreasing exercise tolerance or exercise-associated decrease ≥10 mm Hg in systolic blood pressure, very severe AS (V_{max} ≥5.0 m/s), serum B-type natriuretic peptide (BNP) >3 times normal, or progression of V_{max} ≥0.3 m/s per year (Class 2a). In addition, intervention can be considered among asymptomatic patients with severe high-gradient AS and a progressive decrease in LVEF to <60% on ≥3 serial imaging studies (Class IIb).

6 Among patients in whom a bioprosthesis is appropriate, decisions between surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI) should include the presence of symptoms, patient age and anticipated life expectancy, the indication for intervention, predicted surgical risk, and anatomy or other factors referable to transfemoral (TF) TAVI feasibility (all Class 1):

- SAVR is preferred among patients <65 years of age or with life expectancy >20 years.
- SAVR is preferred if vascular anatomy or other factors preclude TF TAVI.
- SAVR is preferred among asymptomatic patients with a Class IIa indication for intervention, such as an abnormal exercise test, very severe AS, rapid progression, or elevated BNP.
- If feasible, TF TAVI is preferred among patients >80 years of age or with life expectancy <10 years.
- SAVR or TF TAVI is recommended after shared-decision making among symptomatic patients ages 65-80 years with no contraindication to TF TAVI.
- TAVI is preferred among symptomatic patients of any age with high or prohibitive surgical risk, if predicted survival after intervention is >12 months with an acceptable quality of life.
- After shared-decision making, palliative care is recommended among symptomatic patients with predicted post-TAVI survival <12 months or for whom minimal improvement in quality of life is expected.

7 Among patients with asymptomatic severe (Stage C) AR, the disease is subcategorized based on LVEF and LV end-systolic diameter (LVESD). Stage C1 reflects normal LVEF (≥55%; previously ≥50% in the 2014 AHA/ACC guidelines) and mild to moderate LV dilation (LVESD <50 mm). Stage C2 reflects abnormal LV systolic function (LVEF <55%; previously <50%) or severe LV dilation (LVESD 50 mm or indexed LVESD >25 mm/m2; unchanged from previous).

8 Intervention for severe AR is based on the presence of symptoms or LV systolic dysfunction (LVEF ≤55%; both Class 1); or the presence of severe LV dilation (LVESD >50 mm or indexed LVESD >25 mm/m^2; Class IIa).

9 Among patients with BAV, transthoracic echocardiography is recommended to assess valve morphology, assess AS and AR, assess the aortic root and ascending aorta, and evaluate for the presence of aortic coarctation. If the aortic sinuses, sinotubular junction and ascending aorta cannot be accurately or fully assessed on echocardiography, then cardiac magnetic resonance angiography or computed tomography angiography is indicated. Lifelong serial imaging is indicated if the aorta diameter is ≥4.0 cm.

10 Among patients with BAV, indications for replacement of the aorta remain similar to previous: aortic diameter >5.5 cm (Class I), aortic diameter 5.0-5.5 cm plus an additional risk factor for dissection (family history of dissection, aortic growth >0.5 cm per year, aortic coarctation; Class IIa), or aortic diameter ≥4.5 cm with an indication for SAVR (Class IIa).

Read More

Read the rest of the three-part Key Perspectives series on *ACC.org*.

Scan this QR code for the Key Perspective focused on mitral stenosis, mitral regurgitation and tricuspid valve disease.

Scan this QR code for the Key Perspective focused on mixed valve disease, prosthetic valves, infective endocarditis (IE), and pregnancy and valvular heart disease.

New Year, New Opportunities For Cardiovascular Care Transformation

Embracing the Pandemic as a Disruptor and Innovation Catalyst

The world has experienced a year unlike any other in this generation, putting 2020 in the history books as the year of COVID. As 2021 begins, it's important to take time to consider the long-term impacts from the pandemic on the health care industry and patient care. Although history books will focus on the *pandemic* of 2020, the health care industry could, and should, focus on the *disruptor* of 2020.

A disruptor is defined as something that interrupts an event, activity or process by causing a disturbance or problem. A disruptor can also be a force for good when it causes radical change in an existing industry or market by means of innovation, a concept often highlighted in the business industry but rarely used in conjunction with changes in the health care industry.

The current trajectory of health care in the U.S. is not economically sustainable and not maximally effective. Accordingly, health care leaders and society at large agree change is needed. As opposed to small, incremental improvements, the health care industry needs a significant disruption. Viewed through the lens of disruption, innovation and care transformation, there is no opportunity for change like the present.

The pandemic has created economic instability for most health care organizations and providers. Other effects include less than desired patient outcomes from poor access; missed care opportunities; worsening of existing health disparities due to lack of resources and technology needed to seek health care; and a burned out health care workforce. While these challenges aren't new, they've been amplified by the pandemic and there's an increased urgency to implement solutions.

Historical events, such as the 1918 flu pandemic, have provided valuable insights into the effects of a public health emergency, both short- and long-term. From a health care delivery standpoint, many governments embraced new concepts of preventive medicine and socialized medicine after the 1918 flu pandemic. The U.S. also adopted the employer-based insurance plans that expanded access to health care for the general population.[1] Fast forward to the 2020 pandemic and there are many opportunities for innovation in cardiovascular care with hints at transformation, but no clear path to achieving true transformation. If the 2020 pandemic is not seized as a disruptor and catalyst for innovation and care transformation, it will be a missed opportunity.

Disruption creates a need for action. For some, the action will be to look inward and make changes to do more with less. Others will look externally to see how the disruption has changed the industry and patient and provider needs, and look to innovate and transform to better meet those needs. A review of this concept in the business industry suggests looking inward often leads to demise, while looking outward can lead to expansion into new services and markets, creating a trajectory otherwise unforeseen.[2]

Applying Disruption, Innovation to Cardiovascular Care

There is a significant body of literature about leadership in health care. Effective organizations bring the right people to the table with requisite skills in both management and leadership.[3,4]

Cardiovascular programs need an effective leadership and management structure to provide vision and foster an environment supportive of innovation and transformation. Applied to surviving during a time of disruption, management will tend to concentrate on preserving and improving the status quo, while leadership is about challenging the status quo and creating something different and more effective.[5]

Where does a program start? Here are three types of innovation described by Regina Herzlinger, Harvard Business school faculty,[6] viewed through the lens of the COVID pandemic.

1 Change the Way Consumers Buy and Use Health Care

Early in the pandemic, MedAxiom described the rapid transition to virtual care through telehealth services in its "Survey Report: Impact of COVID-19 on Cardiovascular Organizations," published in April 2020. The survey found most programs transitioned to a virtual delivery model in less than two weeks and changes in reimbursement and regulations that supported the transition closely followed.

Numerous learnings stemmed from the transition to virtual care delivery. The transition highlighted the capabilities and ability to do this work effectively while putting a spotlight on disparities in access to health care. Patients without access to technology had an even harder time receiving needed care.

Further, the early pandemic forced a shift from preventive, routine care to urgent-only care. Many stories have been shared about patients who waited too long to seek care or missed routine evaluations only to present with acute needs. A shift in the health care delivery model needs to recognize these disparities and assure access to routine, preventive care, as well as urgent needs. Virtual care worked, and needs to stay, but must evolve. A digital transformation must complement face-to-face care such that virtual care be embedded when and where it is most effective for communication, care coordination and care delivery.

2 Use Technology to Develop New Products and Treatments

Device therapies, pharmacologic therapies and procedural therapies have all progressed in recent years. Innovations are allowing clinicians to make earlier diagnoses and providing tools for effective primary and secondary prevention. In coronary artery disease, noninvasive imaging technologies are emerging that provide both anatomic and functional data to better define risk and can guide management strategies. The anticipated result is a shift toward health maintenance

How are you handling the majority of new patient scheduled visits?

51.7%	19.5%	28.7%
Keeping scheduled face-to-face appointments	Seeing via telehealth, virtual, etc.	Triaging and rescheduling to a later date

Source: MedAxiom Survey Report: Impact of COVID-19 on Cardiovascular Organizations, April 2020

with reduced need for, and more effective use of, invasive treatment options. A recent article in the *Journal of the American College of Cardiology* by Ferraro, et al, provides a disruptive example using the evaluation and treatment of patients with stable angina with a CT-guided algorithm.[7]

There are many other examples that will have an impact on workforce needs, skillsets, operational processes and changes in both provider and patient expectations. Team-based, multidisciplinary care will promote effective and efficient care. The pandemic has caused programs to redeploy providers, develop new care pathways and redefine relationships with hospitalists, emergency departments, intensivists and with each other. This redeployment of providers, which utilizes skillsets in unique ways, was an innovation and proved the cardiovascular industry's ability to adapt. Barriers that were economic and related to "turf" were broken down with ease and grace. However, solutions to support long-term transitions are required and reimbursement changes and physician compensation models must adjust to support/encourage team-based care delivery. The work must happen at a pace that will support innovation and a true transformation of care.

3 Generate New Business Models that May Involve Horizontal or Vertical Integration of Separate Health Care Organizations or Activities

The traditional fee-for-service model is at a tipping point. The pandemic has shown that a reactive care delivery model in a fee-for-service funded environment is ineffective. Limitations to elective procedures, ambulatory care services and overall reluctance to seek health care has created an economic perfect storm for health care organizations. In addition, nonacute services that utilize acute care hospitals as their site of service came to a halt. This created both economic struggles and more importantly missed care opportunities.

> Viewed through the lens of disruption, **innovation and care transformation,** there is no opportunity for change like the present.

The cardiovascular industry recognizes the opportunity to transition many services to ambulatory surgical centers (ASCs) and office/outpatient departments. The pandemic has highlighted that having nonacute care sites of service is important. An example of a recent delivery innovation in the cardiovascular space is the transition of PCI to an ASC. A position statement from SCAI in May 2020 stated: "the ability to perform PCI in an ASC has been made possible" and is happening effectively when structured appropriately.[8] However, full adoption will require multiple changes including health policy, economic alignment, facility planning, integration models and operational structures.

Looking Forward

As tragic as the last year has been, there is an opportunity to use the disruption to create positive, lasting change. Dyad leadership, a vision for innovation and embracing lessons learned will allow true cardiovascular care transformation. Vision and leadership are the key ingredients in the innovations that will transform care. The ACC and MedAxiom have a joint mission: "To transform cardiovascular care and improve heart health." We are in the business of care transformation and will work tirelessly to lead members with vision, education, organizational resources and advocacy. Let's transform cardiovascular care, together.

Visit *MedAxiom.com* to learn more about cardiovascular care transformation efforts.

References are available with the online version at ACC.org/Cardiology.

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ACC Advocacy: Top 10 Highlights of 2020

The COVID-19 pandemic, while testing the limits of resilience and requiring unprecedented flexibility and creativity, also underscored the importance and value of advocacy. From the very onset of the pandemic, ACC Advocacy leaders and staff proactively sprang into action to deliver solutions aimed at helping cardiovascular patients, clinicians and institutions navigate the many challenges posed by the virus.

Moreover, other health policy activities didn't stop for the pandemic and members and staff worked hard to deliver on the College's key Advocacy priorities related to reducing administrative burden and promoting clinician well-being; leading the transition to models that strengthen value and patient outcomes; promoting practice stability and patient access to affordable care; optimizing care, outcomes and health; and advancing member engagement and leadership.

The top 10 Advocacy highlights from 2020 help to illustrate the many ways ACC Advocacy is working to deliver on the College's Mission and Vision.

COVID-19 FUNDING

1

Thanks to a record-breaking 12,000 grassroots messages and persistent lobbying efforts, Congress passed four COVID-19 legislative packages over the course of 2020, bolstering supply of personal protective equipment, ventilators, and diagnostic testing while also creating the Provider Relief Fund and the Paycheck Protection Program to help practices remain financially stable.

TELEHEALTH FLEXIBILITIES

2

In response to feedback from the ACC and others, Congress directed the Centers for Medicare and Medicaid Services (CMS) to broaden access to telehealth during the COVID-19 public health emergency (PHE), removing obstacles such as originating site and platform requirements, and ultimately also allowing for cardiac and pulmonary rehabilitation services.

TELEHEALTH REIMBURSEMENT

3

Thanks to ACC Advocacy efforts underscoring the value of telehealth, CMS, along with numerous commercial payers, agreed to pay the same rate for many telehealth services as in-person services. Also of note, discussions with policymakers convinced public and several private payers to recognize patients' need for audio-only telehealth services with payment at similar rates to audio-visual telehealth. Visit ACC's COVID-19 Hub (*ACC.org/COVID19*) for telehealth resources from both the College and MedAxiom.

BUDGET NEUTRALITY

4

Responding to the concerns of ACC and others, Congress added funds to the 2021 Medicare Physician Fee Schedule that mitigate statutorily required budget neutrality payment reductions to balance increased payment for evaluation and management (E/M) services.

LEGISLATIVE CONFERENCE

5

The ACC's 2020 Legislative Conference was the largest to date, with 614 participants spanning the entire cardiovascular care team. Virtual educational sessions helped to educate clinicians about the most pressing health policy issues before Congress and a total of 327 virtual meetings were held with members of Congress and/or their staff. **Scan the QR code to learn more and save the date for this year's conference.**

VAD COVERAGE

6

At the urging of ACC, CMS eliminated the outdated intent to treat coverage indications for Ventricular Assist Device (VAD) candidates. **Scan the QR code to read more.**

VALUE-BASED CARE

7

The ACC convened seven national health plans and Medicare leaders through its Value-Based Care in Cardiology Forum in December. The innovative forum focused on developing new payment models for treating recently diagnosed atrial fibrillation patients. **Scan the QR code for more on value-based care in ACC's Alternative Payment Model hub.**

COVID-19 STATE ADVOCACY

8

Efforts by ACC's State Advocacy Team, working closely with ACC's State Chapters, were influential in helping to expand telehealth access, implement health care worker liability protections, and retain appropriate patient access to cardiovascular care as part of numerous state PHE responses.

STATE ADVOCACY

9

ACC State Chapters and ACC grassroots members were successful on several state legislative fronts in 2020, including continued adoption of Tobacco 21 legislation, as well as prior authorization reform.

HeartPAC

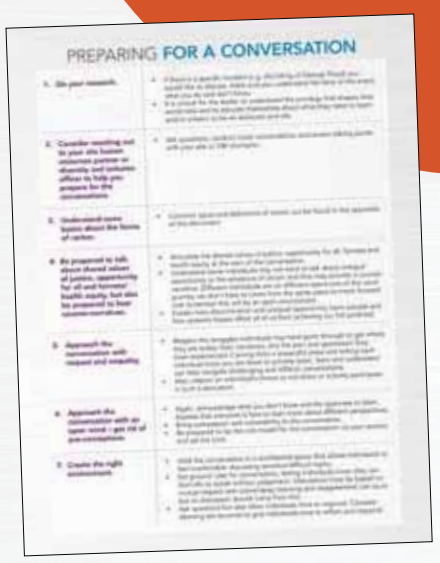
10

Cardiovascular disease doesn't discriminate based on political party. As such, the ACC has a long history of working with members of Congress on both sides of the aisle to advance health policy solutions that are best for cardiovascular patients and clinicians. During the 2020 Election Cycle, ACC's HeartPAC distributed $749,500 to members of Congress, 95% of whom were victorious in their races. Learn more at *HeartPAC.org*.

Learn more about ACC Advocacy at *ACC.org/Advocacy.*

FIVE BEST PRACTICES

For Preparing For Conversations About Racism, Race and Ethnicity in Professional Settings



The ACC strives to lead in diversity, equity and inclusion and seeks to foster a supportive and inclusive culture within our organization and in the cardiovascular community. To help all leaders prepare for facilitated conversations with peers or groups about racism, race and ethnicity in professional settings, the Diversity and Inclusion Task Force developed a discussion guide with techniques that can be used during discussions to foster an open dialogue and suggested steps to take following a discussion to continue the dialogue.

DO YOUR RESEARCH.

- It is critical for the leader to understand the privilege that shapes their world view and to educate themselves about what they need to learn and/or unlearn to be an advocate and ally.

BE PREPARED TO TALK ABOUT SHARED VALUES OF JUSTICE, OPPORTUNITY FOR ALL AND FAIRNESS/HEALTH EQUITY, BUT ALSO BE PREPARED TO HEAR COUNTER-NARRATIVES.

- Articulate the shared values of justice, opportunity for all, fairness and health equity at the start of the conversation. Explain how discrimination and unequal opportunity harm people and how systemic biases affect all of us from achieving our full potential.

APPROACH THE CONVERSATION WITH RESPECT AND EMPATHY.

- Respect the struggles individuals may have gone through to get where they are today, their narratives, and the pain and oppression they have experienced. Coming from a respectful place and letting each person know you are there to actively listen, learn and understand can help navigate challenging and difficult conversations.

APPROACH THE CONVERSATION WITH AN OPEN MIND – GET RID OF PRECONCEPTIONS.

- Acknowledge what you don't know and the openness to learn. Express that everyone is here to learn more about different perspectives. Be prepared to be the role model for the conversation via your actions and set the tone.

CREATE THE RIGHT ENVIRONMENT.

- Hold the conversation in a confidential space that allows individuals to feel comfortable discussing sensitive/difficult topics. Set ground rules for conversation, letting individuals know they can feel safe to speak without judgement.

Scan the QR code for the complete discussion guide for more best practices on what leaders can do to prepare for a discussion on racism, race and ethnicity in the professional setting.

Scan this QR code for ACC's Anti-Racism Resource Center.