



**BEYOND  
INTERVENTION**

## IMPROVING PATIENT EXPERIENCE BY ADDRESSING UNMET NEEDS IN VASCULAR DISEASE

2021 Beyond Intervention White Paper, 18 pages

## ADDRESSING RACIAL AND GENDER BIAS IN CARDIOVASCULAR CARE: WHY IMPROVING HEALTH EQUITY IS AN URGENT NEED FOR THE HEALTHCARE COMMUNITY

Special Supplement, 7 pages



BEYOND  
INTERVENTION

# IMPROVING PATIENT EXPERIENCE BY ADDRESSING UNMET NEEDS IN VASCULAR DISEASE

# INTRODUCTION

Abbott, as a global healthcare company, has the privilege of helping people live better and healthier lives with our life-changing technologies. With that privilege comes the responsibility to innovate and improve access and affordability to healthcare.

Because our medical devices can have a profound impact on the health of people all over the world, we are positioned to drive change in how healthcare is delivered and received. We believe we can have the greatest impact on the world's health by delivering new and better medical products and services designed to meet the needs of the individual patient, their capable physicians, and make the cost of care affordable.

To enable this vision, we must always keep our finger on the pulse of the people that we serve. We know that people are demanding more from their healthcare providers—more health monitoring, more personalized care plans and more analysis. With this in mind, we embarked on a multi-year research study that surveys the perspectives of patients, physicians, and healthcare leaders about the vascular patient journey. This research, titled “Beyond Intervention” provides insights on delivering personalized patient care, enabling data-driven decision making and creating a more connected care continuum.

When reflecting on the latest goals of the Quadruple Aim - balancing the patient experience with population health, the well-being of the care team and reducing costs - these are not the sole responsibility of healthcare systems, we all have a role to play. As part of Abbott's commitment to helping alleviate some of the biggest pain points in the vascular care journey, our research is helping us better understand that the needs of all stakeholders don't need to compete to achieve a common goal.

This research is essential to the work we do as we look to create the future of vascular care around the world. I invite you to review our latest report to identify areas that you can also influence to improve the vascular patient experience in a meaningful way.



A handwritten signature in black ink, reading "Julie Tyler".

**Julie Tyler**

Senior Vice President and President of  
Abbott's Vascular Business

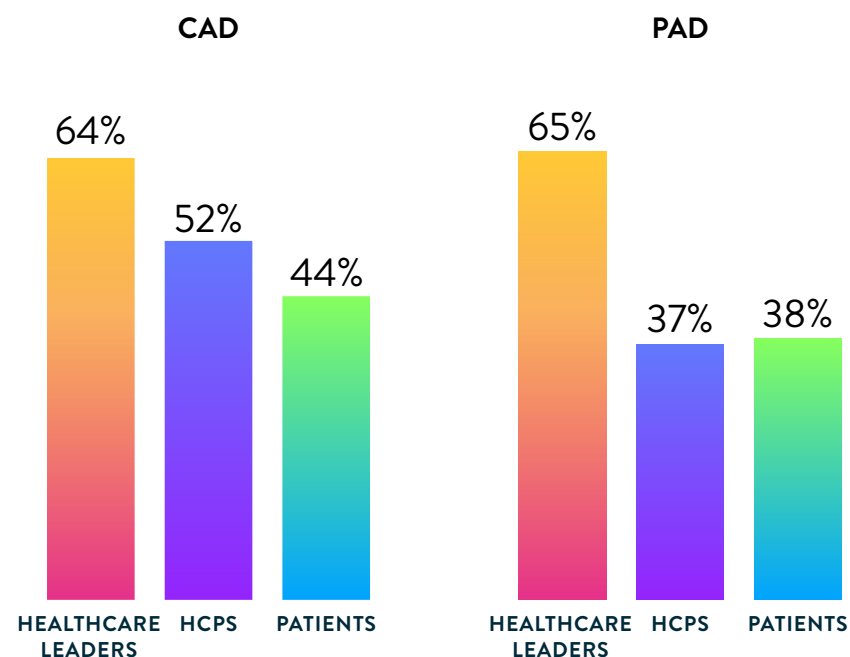
# EXECUTIVE SUMMARY

In Abbott's 2020 primary-research-based white paper, "**Personalized Vascular Care Through Technological Innovation**," the majority of surveyed physicians and healthcare leaders stated that accurate decisions have the most impact either at diagnosis or when determining a patient's treatment pathway. In this year's survey, we have delved further into understanding the challenges that arise within the earliest stages of the vascular patient journey—from screening and symptom detection/recognition to specialist referral.

Our new study explores the differing perceptions and experiences of 1,289 people suffering from vascular diseases across 13 countries—along with 408 physicians and 173 healthcare leaders. A total of 1,800+ stakeholders were surveyed from April to June 2021.

The key findings highlight one crucial truth: The patient experience may not be as good as healthcare leaders and physicians think it is. Our study indicates that healthcare providers are more likely to rate a positive experience for people afflicted with coronary artery disease (CAD) and peripheral artery disease (PAD) than the patients themselves (see chart). Interestingly, although healthcare leaders are stable in their impressions across the CAD & PAD patient experience, physicians also recognize key gaps in PAD care as the PAD patient experience can be even more difficult with multiple, complex conditions contributing to a less well-defined, non-classical symptom presentation, or when medical care is not easily accessible.

Percentage of HCPs/healthcare leaders who agreed the current patient experience is ideal vs. percentage of patients who agreed their experience went as well as it could have.



The key findings highlight one crucial truth:  
The patient experience may not be as good as healthcare leaders and physicians think it is, with healthcare leaders especially disconnected from the nuanced challenges of PAD care.

The survey uncovered three key areas noted by physicians, healthcare leaders and patients that impede or negatively impact the patient journey. These are:

- 1 Lack of awareness of symptoms and treatment options**—Many people with vascular diseases are unaware of their condition, tend to downplay their symptoms, and/or are confused about the next steps they should take for diagnosis and treatment.
- 2 Lack of standardized processes and technologies for diagnosis**—Accurate diagnoses are challenged by numerous variables cited by physicians such as lack of equipment and technology, and lack of a standardized approach to diagnosis.
- 3 Lack of coordination and communication among PCPs and specialists**—Patients remain dissatisfied with the amount of face time they have with their physicians, and they are equally unhappy with the communication—or lack thereof—between their primary care physicians and their specialists.

There is clinical evidence that early detection and diagnosis of patients who are at risk of developing vascular disease, and then are treated, have experienced a significant reduction in coronary events.<sup>1</sup> Thus it's important to identify the gaps in the earliest stages of patient care, and for healthcare organizations to acknowledge how the patient care continuum is more than just a journey - it impacts patient experience.

\*We used the following weightings (on a scale of 5) to determine whether patients were “less” underserved, “moderately” underserved, or “highly” underserved: Difficulties affording food (1.75), Difficulties affording medicine (1.5), Avoids medical care due to costs (1.0), Lower income than others in state/region (0.5), Has access to transportation when needed (0.25).

Based on these weightings, we determined that 27 percent of our underserved respondents fall into the “less underserved” category (receiving a score of 0.25-1.5), 13 percent into the “moderately underserved” category (receiving a score of 1.75-3.5), and 11 percent into the “highly underserved” category (a score of 3.5+). Nearly half at 49 percent were deemed not underserved (a score of 0).

Our report examines the potential of these various technologies to improve symptom detection/recognition and diagnostic processes, while simultaneously easing the pain points to optimal care for vascular patients worldwide. Based on the results of our research and the clinical evidence, healthcare providers, the medical technology industry, and patients themselves should consider the following opportunities and actions for improving the vascular care experience:

- 1** Acknowledge that each patient journey entails unique challenges (especially for PAD patients, the underserved\*, women, and people with diabetes), with an imperative to increase early-onset awareness of disease symptoms, their variability and significance, and consequent therapeutic options.
- 2** Address challenges to early and accurate diagnostic testing, including patient access to physicians and appropriate resources—and, equally important, physician access to proper tools.
- 3** Link pre-existing sources of disparate patient information to ensure seamless coordination and communication between primary care providers (PCPs) and specialists.

Patients continue to wield more power in their healthcare choices, and technology provides further opportunities for understanding and owning their own data. Through standardization of key technologies and screening methodology, physicians can provide patients more personalized, individualized care when diagnosing and treating vascular disease—ultimately achieving a better care experience.

## AN IMPERATIVE TO ADDRESS THE INCREASING CONSUMERIZATION OF HEALTHCARE

To develop and deliver patient-forward solutions, providers must account for the rapidly increasing “consumerization” of healthcare, led by increased patient empowerment. Patients are embracing technology and other avenues to play a more active role in their own health—a tectonic shift that potentially threatens continuity of care within the traditional model of healthcare delivery.

A wide range of technology tools now provide quick and easy ways for consumers to access information on health issues and costs, monitor their own health conditions, order prescription drug refills, and play a major role in making care-related decisions—including telling doctors when they disagree with them. One key factor that may be influencing this trend is the increasing cost of care. According to Kalorama Information, patient out-of-pocket healthcare costs have risen 10 percent since 2020.<sup>2</sup>

For these and other reasons, organizations need to gain a better understanding of patients as healthcare consumers, along with crafting strategies that meet their evolving needs.

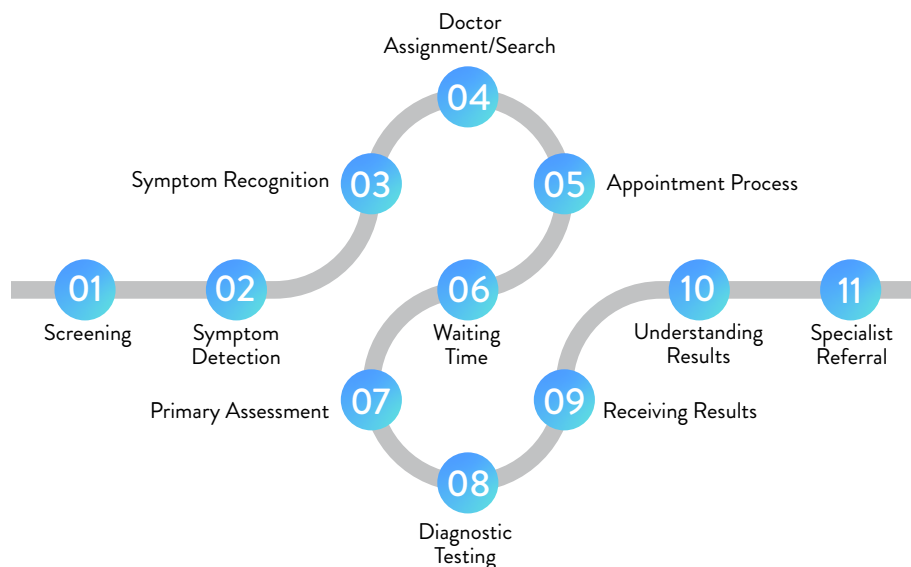
Unfortunately, most providers haven’t sufficiently modified their services to meet the changing expectations of today’s digitally savvy healthcare consumers. One recent study found that just 8 percent of US hospitals and health systems demonstrate strong consumer-centric performance—and that 70 percent of these organizations either have not begun their consumerism efforts or are in the very early stages.<sup>3</sup>

“Too often, healthcare providers forget that patients are also consumers,” explained Dr. Peter Fitzgerald, Professor Emeritus in Medicine at Stanford University. “In the United States, for example, the increasing consumerization of healthcare is encouraging companies from other industries such as retail, entertainment, social media, and information technology to get more involved in addressing their customers’ healthcare-related needs. Because companies in these industries are experts at engaging consumers, healthcare providers have much to learn from them.”

To boost customer satisfaction and retain patients, it’s imperative that providers revamp their services by using technology to increase transparency, access, and ongoing engagement outside the clinic.<sup>4</sup>

## UNMET NEEDS IMPACTING PATIENT EXPERIENCE

**This year’s survey evaluated the experiences of CAD and PAD patients across 11 steps of the care journey, from symptom detection to diagnosis:**



### Here’s what we learned:

Patients experience the most difficulty with:

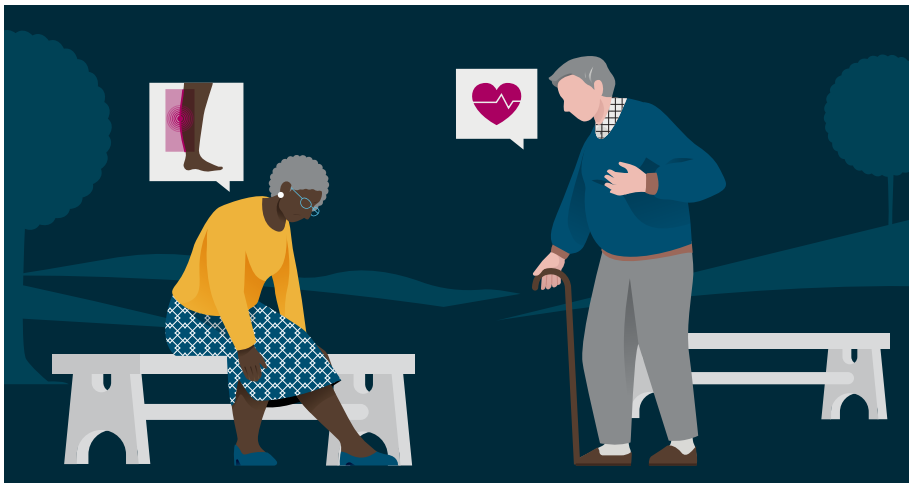
- (1) symptom detection/recognition
- (2) diagnostic testing, both of which can be exacerbated by
- (3) a system with poor coordination between primary care providers and specialists

Let’s take a closer look at how survey respondents view these three critical issues.

## KEY ISSUE NO. 1: Lack of Awareness of Symptoms and Treatment Options

Many people with vascular diseases are unaware of their condition; they tend to downplay their symptoms, and/or are confused about the next steps they should take for diagnosis and treatment:

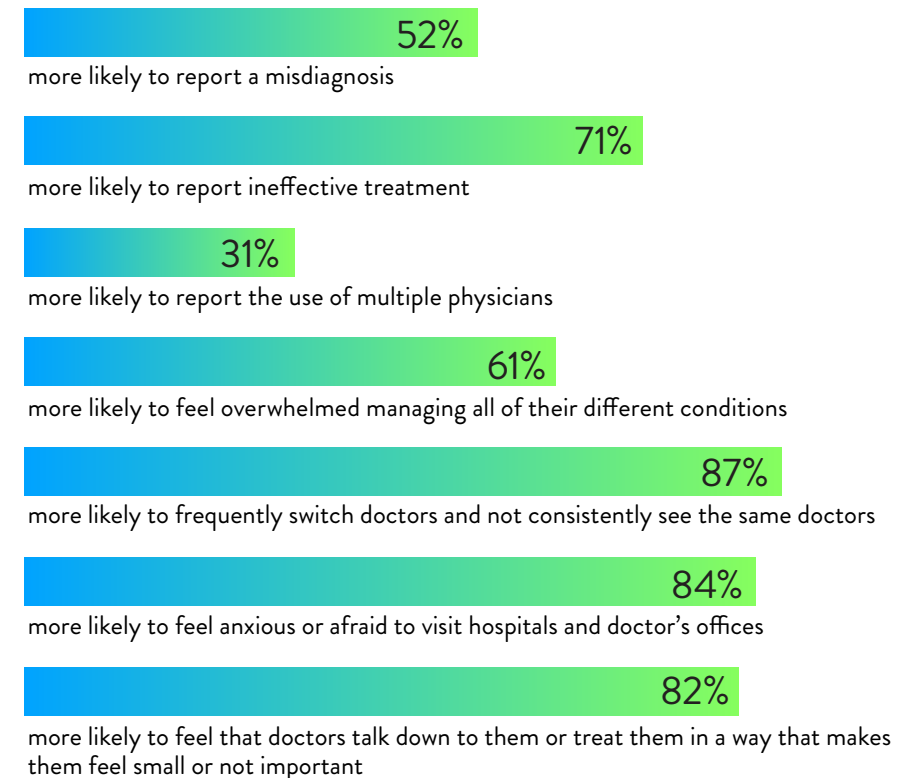
- About half of surveyed CAD and PAD patients cited “struggles with recognizing symptoms/not realizing the problem before it became an emergency.”
- Around 2 in 5 surveyed CAD and PAD patients selected “not thinking my symptoms were a big deal” and “not thinking they were worth mentioning to my doctor” as key barriers to their diagnosis and treatment (also a heightened trend for men compared with women).
- Over a third of surveyed CAD and PAD patients named “confusion about what I was supposed to do next” as an important barrier to early and accurate diagnosis.



“It was my fault for ignoring symptoms for over a week before seeing my primary care doctor,” admitted a 75+-year-old female patient respondent from the United States. “Easier identification of symptoms would have made it much simpler to find the right doctor,” added a 35- to 44-year-old male respondent from India.

Based on our study, it appears that PAD patients face an even greater number of challenges to early and accurate diagnosis than their CAD counterparts, including difficulty navigating the healthcare system, lifestyle challenges, and poor physician/care provider sentiment (see chart).

### Compared to CAD Patients, PAD Patients are:



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Dr. David G. Armstrong, Professor of Surgery and Director of Limb Preservation at Keck School of Medicine at USC, recommends that the industry adopt “red/yellow/green” screening techniques to help triage patients and determine the next steps for effective treatment. “Ultimately, we need to develop teams to bring awareness of symptoms and diagnostic/treatment techniques forward to the industry,” Dr. Armstrong explained. “To accomplish this, it will be important to highlight patterns of success through key case studies.”

”

## KEY ISSUE NO. 2: Lack of Standardized Processes and Technologies for Diagnosis

Our study shows that roughly 1 in 5 PAD and CAD patients state they were misdiagnosed on average three times before receiving a diagnosis for their symptoms—and PAD patients are significantly more likely to see multiple physicians, which may make it more difficult to share relevant information.<sup>5</sup>

Care providers say that the accuracy of their diagnoses is being challenged by the lack of a standardized approach or technology/equipment for diagnosing CAD/PAD:

- ~1 in 4 physicians feel that “lack of technology or equipment to accurately diagnose CAD/PAD” is a key obstacle to an accurate diagnosis.
- ~1 in 3 healthcare leaders believe that a “lack of standardized approach for diagnosing CAD/PAD” is a key obstacle to an accurate diagnosis.

This situation feeds one of patients’ biggest frustrations that surfaced in our research: not receiving a clear diagnosis—even after making multiple office visits. Our study shows that, on average, doctors see patients **three times** before referring a patient with CAD symptoms to a specialist, compared with **four visits** before referring a patient with PAD symptoms.

When diagnosing patients with PAD—which can be challenging due to the fragmented care journey of these patients, who are more likely to be juggling multiple conditions—physicians stated they were less confident in the areas of symptom recognition, selecting the right diagnostic tools, interpreting results, and referring patients to the right specialists as compared to physicians diagnosing patients with CAD.





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Dr. Natalia Pinilla, Interventional Cardiologist at Hamilton Health Sciences/Niagara Health, points out that inherent biases can also hinder physicians' ability to detect and recognize symptoms in CAD and PAD patients—particularly for populations that are known to have less prevalence of vascular disease as young, female and/or certain ethnicities; but having a lower prevalence does not rule out a diagnosis of CAD/PAD. “Females are a special population known to express symptoms differently, making it quite difficult to interpret, leading to disregarding symptoms and often delaying care and diagnostic testing—they are sent home with outpatient follow up with the message that CAD or PAD are unlikely diagnosis,” Dr. Pinilla explained. “We need better risk-factor screening tools to minimize bias and over-reliance on individual perspectives. Knee-jerk responses from physicians can cause problems for patients—either through unconscious bias or simply because patients of different sex and ethnicities present differently.”

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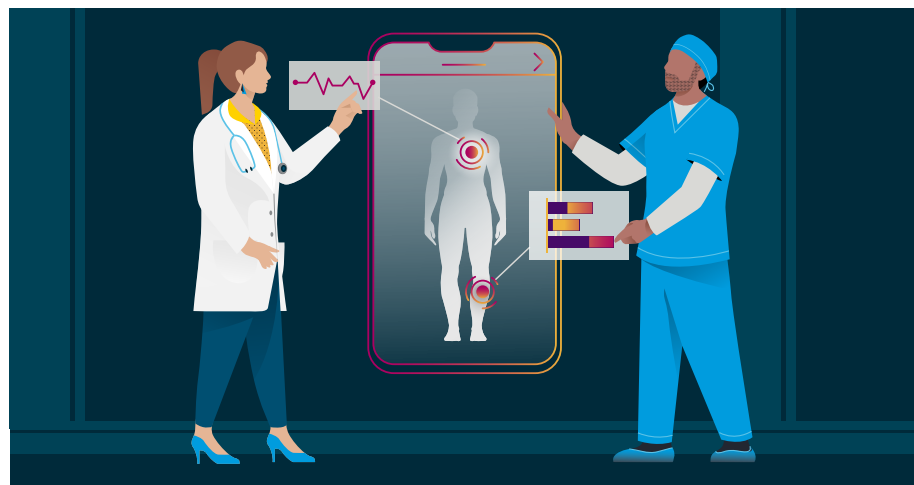
Dr. David Rhew, Global Chief Medical Officer and VP of Healthcare at Microsoft, believes that the keys to better, more standardized patient screening are expanded education programs and adoption of the right technologies. “We need to get better at identifying the right patients at triage and post-event—such as whether, for example, a CAD patient is also likely to have PAD,” he explained. “We also need to be able to spot signals that we may be missing, such as through routine imaging procedures occurring elsewhere in the hospital. And, finally, we need to stop treating CAD as an isolated illness. Because those with CAD likely have PAD, seeing a patient with CAD should also trigger actions to evaluate the rest of the vasculature.”

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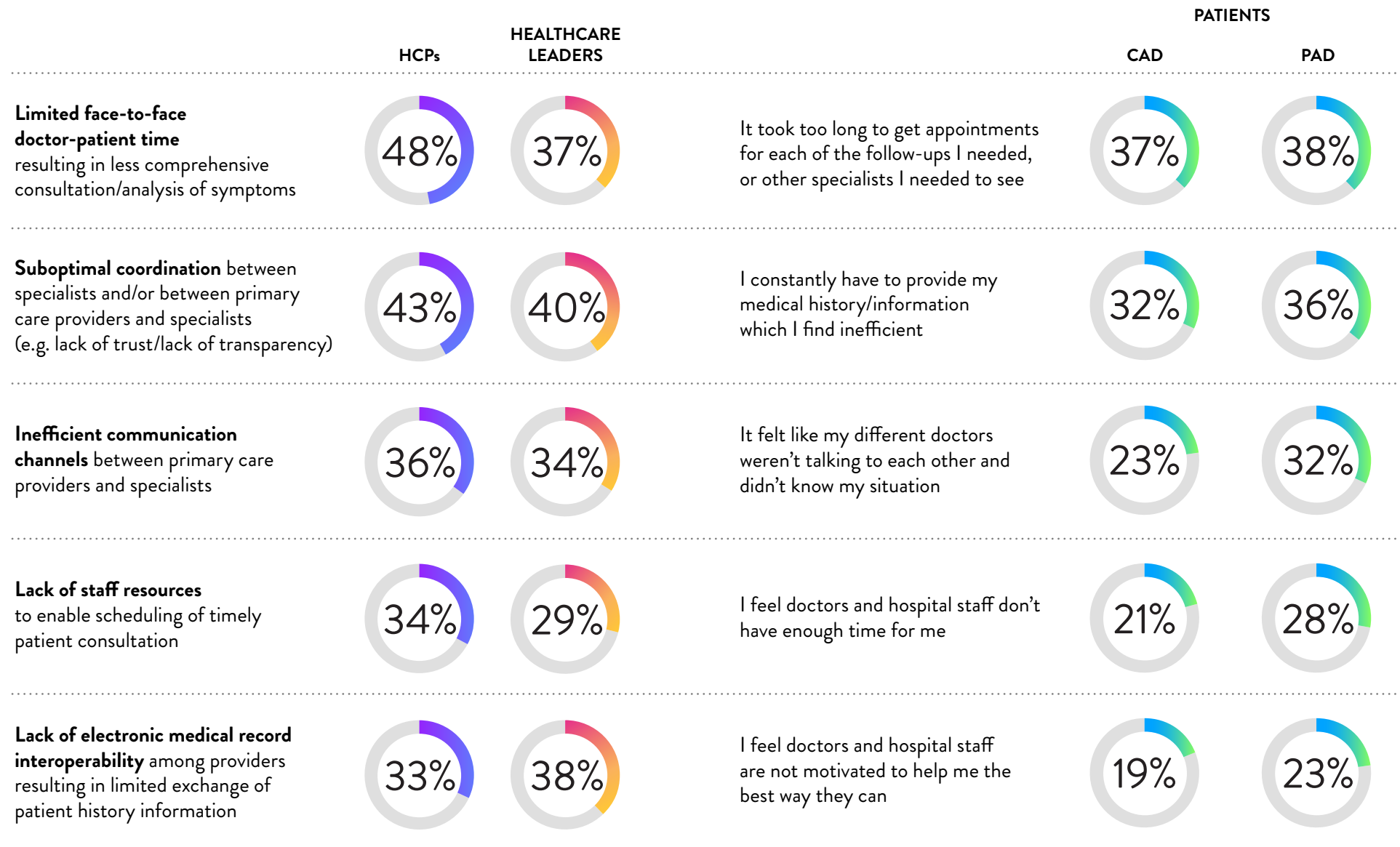
### KEY ISSUE NO. 3: Lack of Coordination and Communication Among PCPs and Specialists

“Limited face time” topped the list of challenges to early and accurate diagnosis cited by physicians and healthcare leaders in this year's survey, consistent with last year's results. However, there are two other interrelated pain points that surfaced in our latest survey: “suboptimal coordination/communication between primary care providers and specialists” and “lack of electronic medical record (EMR) interoperability” (see chart on next page).

Patients seem to agree. In this year's survey, roughly a third of CAD and PAD patients cited “I constantly have to provide my medical history/information, which I find inefficient” as one of the top challenges to early/accurate diagnosis. In addition, about a third of PAD patients and nearly a quarter of CAD patients cited “I felt like my different doctors weren't talking to each other” as a top challenge.



## Hospital and Staff-Related Barriers for Early and Accurate Diagnosis



Time to get an appointment and constantly providing medical history are the top barriers picked by patients, followed by suboptimal physician coordination and perception of limited physician attention.

Describing her experience with lackluster communication among care providers, an underserved 75+-year-old patient from the United Kingdom complained, “The hospital should have informed my doctor of my heart attack and medication. He said that he had no knowledge of what I was talking about and did not roll out my lengthy prescription renewal. He took me off all hospital-based prescriptions. I wept with frustration and fear.”

According to physician respondents to our survey, antiquated, cumbersome processes are a major contributor to the communication problems that exist among primary care providers and specialists—ultimately producing a fractured patient journey. “Getting correspondence—either written or verbal—is difficult,” explained a general practice physician from the United States.

Some general cardiologists expressed frustrations about the quality of referrals and other communications they receive from primary care providers. Others expressed interest in exploring specific ways to build closer relationships through open dialogue or discussions, training, and other opportunities. “We need increased joint education and direct follow-up discussions following procedures,” stated a general practice doctor from the United States. An internal medicine doctor from India added, “We need to meet more often and discuss cases on the basis of current evidence.”

## EMERGING TECHNOLOGY OPPORTUNITIES CAN HELP EASE PATIENT EXPERIENCE CHALLENGES

The three issues outlined in this paper have taken a significant toll on the overall experience of CAD and PAD patients. For example, nearly a third of PAD patients and over a quarter of CAD patients responding to our survey believe that certain aspects of their care could have been better. In general, younger patients and underserved populations reported worse experiences than other CAD and PAD subgroups in our survey (see appendix for more information).

According to our patient respondents, physicians can earn greater trust (and thus improved patient satisfaction) by providing more information to patients—including a personalized treatment plan based on the latest available evidence. This can be supported by providing resources to help physicians identify key variables when distilling the many patient data points provided to them in an increasingly noisy environment. Technologies such as AI and the use of digital health interventions have helped significantly in this space, the latter of which may improve patient healthcare self-management and outcomes.<sup>6</sup>

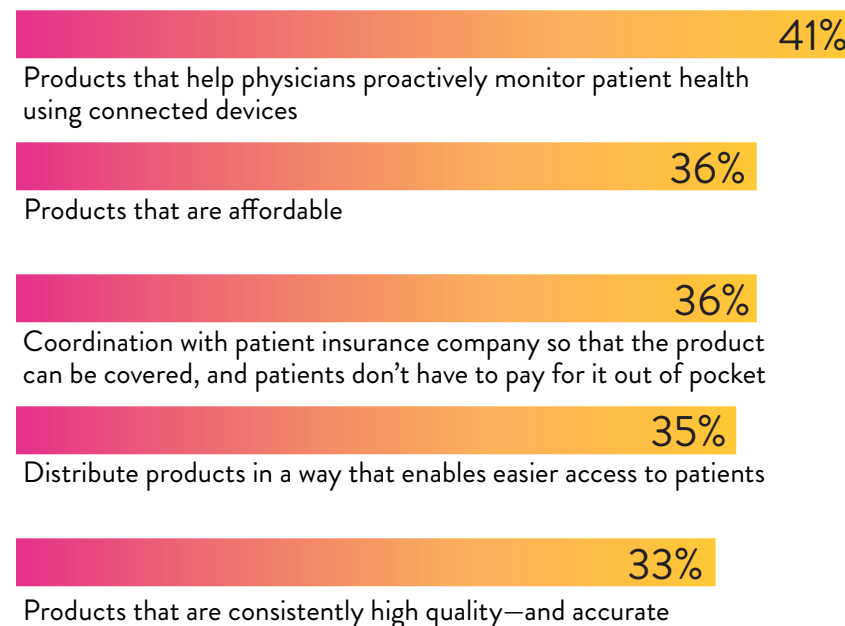
“Whether true misdiagnosis and poor communication occurs is perhaps less important to patients than the perception of such issues, seamless integration of patient records remain a key goal to mitigate such concerns,” stated Dr. Nick West, Chief Medical Officer and Divisional Vice President of Medical Affairs, Abbott’s Vascular Business.

The critical need to improve the patient experience aligns with hospital healthcare leaders' No. 1 priority: patient satisfaction—a change from last year's survey, when cutting costs topped the list for healthcare leaders. When creating patient-centered solutions, it is important to balance healthcare leader expectations; our research shows that healthcare leaders will be focusing on adopting technologies that:

- Help physicians proactively monitor patient health via connected devices
- Are affordable
- Can be covered by patients' health insurance
- Are distributed in a way that enables easy patient access
- Are of consistently high quality—and accurate

The critical need to improve the patient experience aligns with hospital healthcare leaders' No. 1 priority: patient satisfaction—a change from last year's survey, when cutting costs topped the list for healthcare leaders.

#### Adoption of proposed technological solutions can also be increased by understanding healthcare leaders expectations:



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When generalizing use of some of the patient engagement tools, we must be mindful that these technologies may not be a 'one-size-fits-all' solution,” cautioned Dr. Nick West, Chief Medical Officer and Divisional Vice President of Medical Affairs, Abbott's Vascular Business. “Engagement should be tiered to patients' and their carers' desire and level of comfort. For example, some patients want active involvement and monitoring, some will accept passive monitoring, and some simply want to be directed by their medical team. Similarly, not all physicians and healthcare systems will want or be able to embrace these technologies.

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# CONCLUSION AND NEXT STEPS

Our latest research reveals that successful patient outcomes depend on much more than the medical procedure and intervention itself. Variations exist in how people experience the care pathway to diagnosis, treatment, and recovery, driven by factors such as disease state, socioeconomic status, and inter-physician communication. These dynamics can influence and sometimes impede awareness of disease, information sharing, a timely and accurate diagnosis, and the vital connections designed to make patient care more equitable, accurate, and personalized.

“With consumerization of the healthcare experience and increasing patient engagement, responsiveness from healthcare providers holistically is needed at a level never seen before,” explained Dr. West. “Provision of appropriate products, services, and solutions to address these needs is critical to improving patient experience and satisfaction across the entire care continuum.”

Medical technology companies have an opportunity to help physicians and healthcare leaders improve the patient care journey—particularly in the earliest stages. Dr. Rhew comments on the opportunity, stating “Virtual-based technologies such as telemedicine and remote patient monitoring expand patient access to care and facilitate timely exchange of information between patients, caregivers, and healthcare providers. When combined with data analytics and AI/ML, virtual care can facilitate proactive and more efficient care.”

## Here are some actions technology companies and healthcare organizations can consider to help address some of the issues outlined in this report:

**1** Pursue standardized technology tools, processes, and training that enable physicians to make faster, more accurate, individualized diagnosis and referrals—including continuing physician and patient education on disease state awareness and symptom identification. Discrepancies in different patient experiences must be taken into consideration, making the case for individualized vascular care.

Patients cannot be ignored in symptom awareness and disease state awareness campaigns: public awareness and health literacy campaigns and other solutions that deliver an improved understanding of their own risk factors (for example, the likelihood that if they have CAD, they suffer from PAD as well) will be imperative as the rise of the “patient as consumer” era ensues.

**2** Focus on developing and adopting solutions that facilitate improved communication among stakeholders, such as remote monitoring tools that also incorporate features valued most by patients. Digital health intervention patient groups had a 52 percent lower risk for 30-day readmissions—compared with an 11 percent reduction for home health visits and 8 percent for cardiac rehab.<sup>7</sup>

**3** Store vascular disease-specific data within IT infrastructure systems (data lakes) that will enable predictive AI algorithms to improve care. Ensure that data is continually updated and tested to reflect real-world data.

## IMPACT OF SOCIOECONOMIC STATUS, AGE, AND GENDER ON THE PATIENT JOURNEY

Abbott's research reveals that the most troublesome points in the vascular diagnostic journey vary not only by disease type (CAD vs. PAD), but also by patients' socioeconomic status, age, and gender.

For example, underserved\* CAD and PAD patients report significantly more challenges related to access, their healthcare providers, and the resulting emotional impact than their non-underserved counterparts. Underserved patients are:

- More likely to **discover their symptoms unexpectedly** and withhold symptoms from their doctor
- More likely to struggle when scheduling appointments, and have to **wait longer for their appointments**
- More likely to have trouble explaining their symptoms, and to **feel less understood by their doctor**
- More likely to **struggle with understanding their results**, feel their doctor didn't answer their questions adequately, and to go online to learn more
- More likely to **report being misdiagnosed** more frequently

Our survey also highlighted the impact of a vascular patient's age on his or her perception of the care experience. In general, younger patients (ages 35-44) are more proactive and anxious pre-diagnosis, while older patients (age 55+) feel better understood and perceive a smoother overall process. Younger patients tend to:

- **Often think their symptoms are not serious enough to contact their doctor:** Nearly half of surveyed 35- to 44-year-old CAD and PAD patients said they "waited a couple of days to see how my symptoms were developing before taking action," compared with just 20 percent of 65- to 74-year-olds.
- **Downplay their symptoms, but investigate their options earlier:** Nearly half of 35- to 44-year-old CAD and PAD patients started doing research immediately upon symptom onset, compared with only 15 percent of 65- to 74-year-olds.
- **Feel more fear and anxiety while waiting to be seen, feel less understood by their doctor, and then subsequently report more difficulties in fully understanding their results.**

We also learned that female CAD and PAD patients report a more challenging experience than their male counterparts—particularly in the areas of finding a reputable physician, experiencing uncertainty and discomfort while waiting for an appointment, and feeling overwhelmed in managing different conditions. Male patients, on the other hand, tend to view their symptoms as less severe and find it easier to get an appointment in less time.

\*We used the following weightings (on a scale of 5) to determine whether patients were "less" underserved, "moderately" underserved, or "highly" underserved: Difficulties affording food (1.75), Difficulties affording medicine (1.5), Avoids medical care due to costs (1.0), Lower income than others in state/region (0.5), Has access to transportation when needed (0.25).

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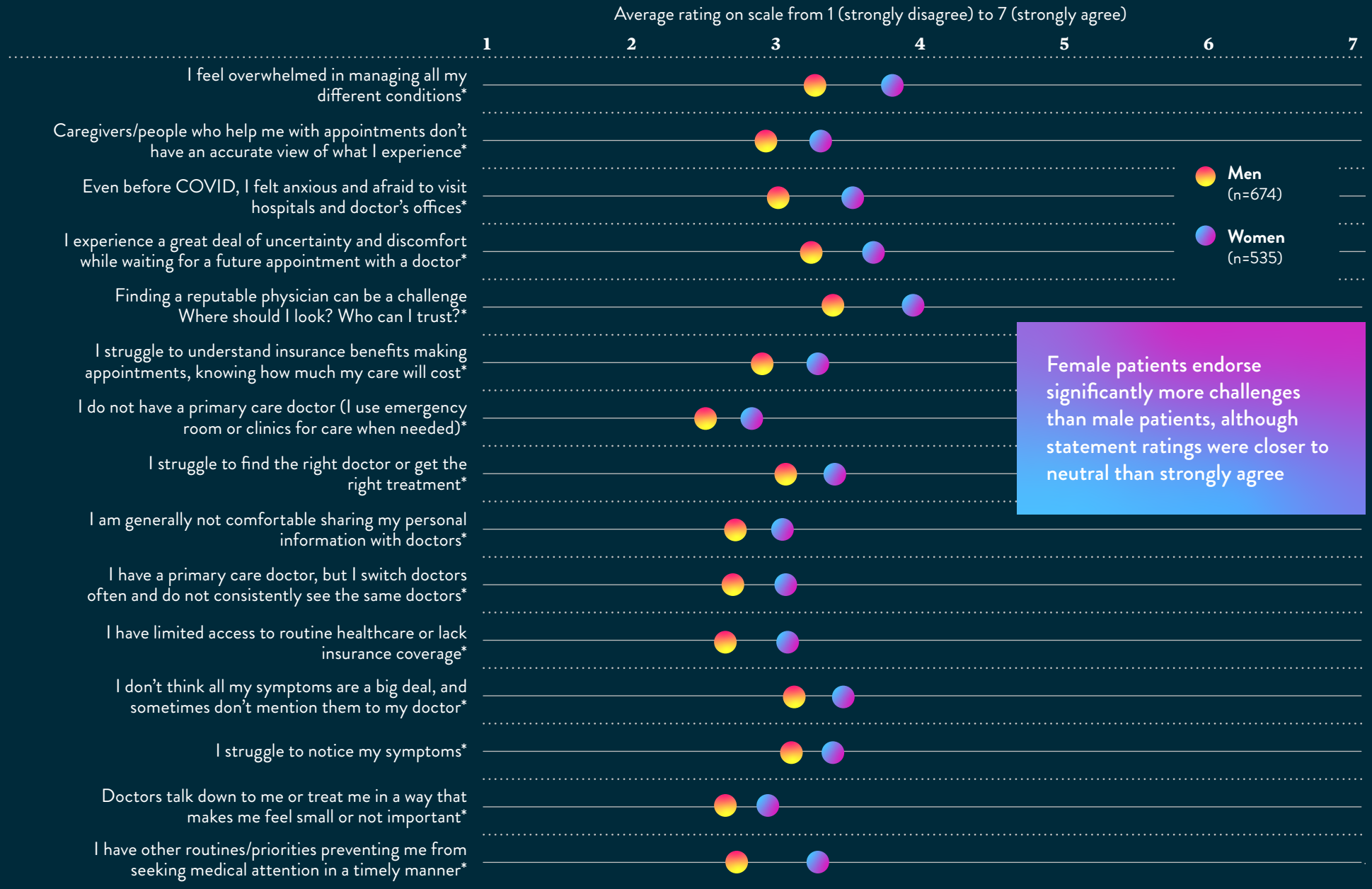
## Patient Characteristics: Underserved Populations

Average rating on scale from 1 (strongly disagree) to 7 (strongly agree)





## Patient Characteristics: Gender



\*Indicates a statistically significant difference between group means at 90% CI.



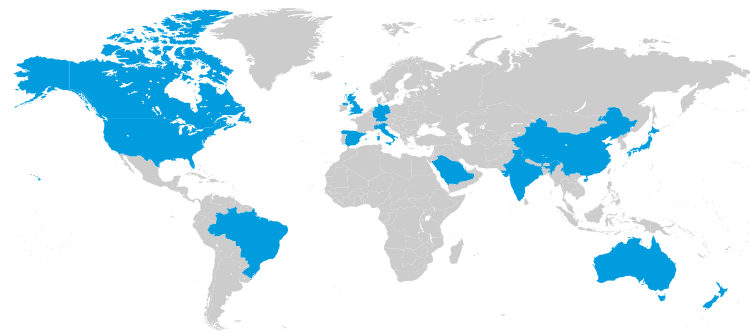
# ABOUT ABBOTT AND THE RESEARCH

For over 135 years, Abbott has been committed to three things:

1) building life-changing technologies that keep people healthy, 2) providing nutritional support and novel medicines, and 3) developing diagnostic tests and breakthrough tools to help people manage their health. Today, Abbott reaches 2 billion people annually through best-in-class products and technologies, with an aim of increasing this to 3 billion (1 in 3 people on the planet) by 2030. As part of this bold mission, Abbott's Vascular business is putting science and innovation to work to create more possibilities for more people.

Our new study highlights the differing perceptions and experiences of 1,289 vascular-disease patients, 408 HCPs, and 173 healthcare leaders across 13 countries: United States, Brazil, Canada, United Kingdom, France, Germany, Italy, China, Japan, India, Australia, New Zealand, and Saudi Arabia. Fielded from April to June 2021, the survey underscores the contrasting experiences of coronary artery disease (CAD) and peripheral artery disease (PAD) patients around the world, along with exploring areas where technology can potentially solve key pain points. The study is a follow-up to last year's "Personalized Vascular Care Through Technological Innovation" worldwide research, which emphasized patients' desire for a personalized, "tailored for me" healthcare experience across the care continuum.

Characteristics of survey respondents were as follows:



	HCPs	Healthcare Leaders	Patients	Total
Canada	30	10	100	140
United States	60	31	150	241
Brazil	35	20	100	155
Germany	41	10	101	152
Italy	27	10	100	137
Spain	27	10	101	138
United Kingdom	28	10	120	158
Saudi Arabia	30	11	100	141
India	30	30	125	185
China	31	21	132	184
Japan	39	0	60	99
ANZ	30	10	100	140
Total # Of Interviews				1,870

## Respondant Selection Criteria

HCP	<ul style="list-style-type: none"><li>• Board-certified/eligible physicians in practice at least 3 years</li><li>• See at least 40 patients per month diagnosed with CAD and/or PAD</li></ul>
Health Care Leader	<ul style="list-style-type: none"><li>• Work in a healthcare setting in a healthcare leader role; in current role at least 3 years</li><li>• Spend at least 60% of time in healthcare leader activities</li><li>• Have direct impact on purchasing for coronary and peripheral interventional products and devices</li></ul>
Patient	<ul style="list-style-type: none"><li>• Age 35+ with self-reported condition associated with CAD and/or PAD</li><li>• Mix of racial/ethnic backgrounds and resourced communities</li></ul>

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# ADDRESSING RACIAL AND GENDER BIAS IN CARDIOVASCULAR CARE: WHY IMPROVING HEALTH EQUITY IS AN URGENT NEED FOR THE HEALTHCARE COMMUNITY

Women suffering from Coronary Artery Disease (CAD) report poorer clinical outcomes and patient experience compared with their male counterparts. Part of this may relate to the documented facts that women present differently in terms of symptoms to men<sup>1</sup> and are underrepresented in clinical trials.<sup>2</sup>

Such unintentional neglect fuels the unintended consequences of conscious or unconscious physician biases in the underdiagnosis and undertreatment of women in routine clinical practice. The resulting worse clinical outcomes for women impact more than the patient alone in terms of the economic burden placed on healthcare systems and the workplace due to repeat hospitalizations and missed workdays.<sup>3,4</sup>

According to the recently-published 2021 ACC/AHA/SCAI guideline

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for Coronary Artery Revascularization, women and non-white patients are less likely to receive cardiac catheterization and more likely to have worse outcomes. Moreover, they are less likely to be recommended for cardiac catheterization by clinicians compared with white male patients, despite sex and ethnicity-agnostic clinical guidelines.<sup>5</sup>

With approximately 112 million people worldwide affected by Ischemic Heart Disease, the prevalence of this disease in women is nonnegligible.<sup>4</sup> While Epicardial Coronary Artery Disease has traditionally been considered the primary cause of myocardial ischemia, around 40-60% of patients with stable angina undergoing elective invasive coronary angiography are found to have no evidence of obstructive disease.<sup>6</sup> This group of patients with symptoms suggestive of Ischemia and No Obstructive Coronary Artery Disease (INOCA) nevertheless have increased morbidity and major cardiac adverse events compared with those without symptoms, with higher prevalence rates in women in the range of 50-70%.<sup>3</sup> Estimates for the economic burden of INOCA alone can be up to \$21 billion.<sup>4</sup>

Marginalizing women's vascular health has clinical and economic consequences that are directly at odds with the ideals of the Institute for Healthcare Improvement's "Triple Aim" initiative, to simultaneously improve population health, improve patient experience and quality of care, and lower the cost of care.<sup>7</sup>

Now, more than ever, it is imperative that the community focuses on gaps in existing data sets that may be unrepresentative or incomplete with respect to this underrepresented half of the population. This could be achieved in three ways, by:

1. Enrolling more representative samples in clinical data studies, starting with more inclusive trial designs
2. Leveraging comprehensive and inclusive data sets for training AI algorithms, which are set to inform future diagnostic and therapy decisions for patients
3. Increasing investments in women's health, incorporating the spectrum of clinical trial grant funding and ranging to Female Technology (FemTech) solutions that can help with disease management

## A Less than Ideal Patient Experience

In recent Beyond Intervention research from Abbott,<sup>8</sup> women suffering from CAD and/or PAD reported more challenging experiences than their male counterparts in all surveyed factors related to access to healthcare, emotional factors surrounding healthcare interactions, and relationships with their physician [see inset on the following page].

In particular, women struggle to find a reputable physician, experience uncertainty and discomfort while waiting for an appointment, feel overwhelmed in managing their different conditions, often underestimate or don't pay attention to their symptoms, and may have other conflicting priorities that prevent them from seeking prompt medical attention.

Extensive reported data suggest that women may simply exhibit inherent differences in how they report or cope with chest pain and those consequent disparities may be rooted in underrecognized gender-specific

pathophysiologies.<sup>1</sup> For patients with INOCA, itself more common in women, their angina may be due to Coronary Microvascular Dysfunction (CMD), which may present differently than an epicardial obstruction and cannot be detected using typical imaging techniques such as angiography.<sup>3</sup>

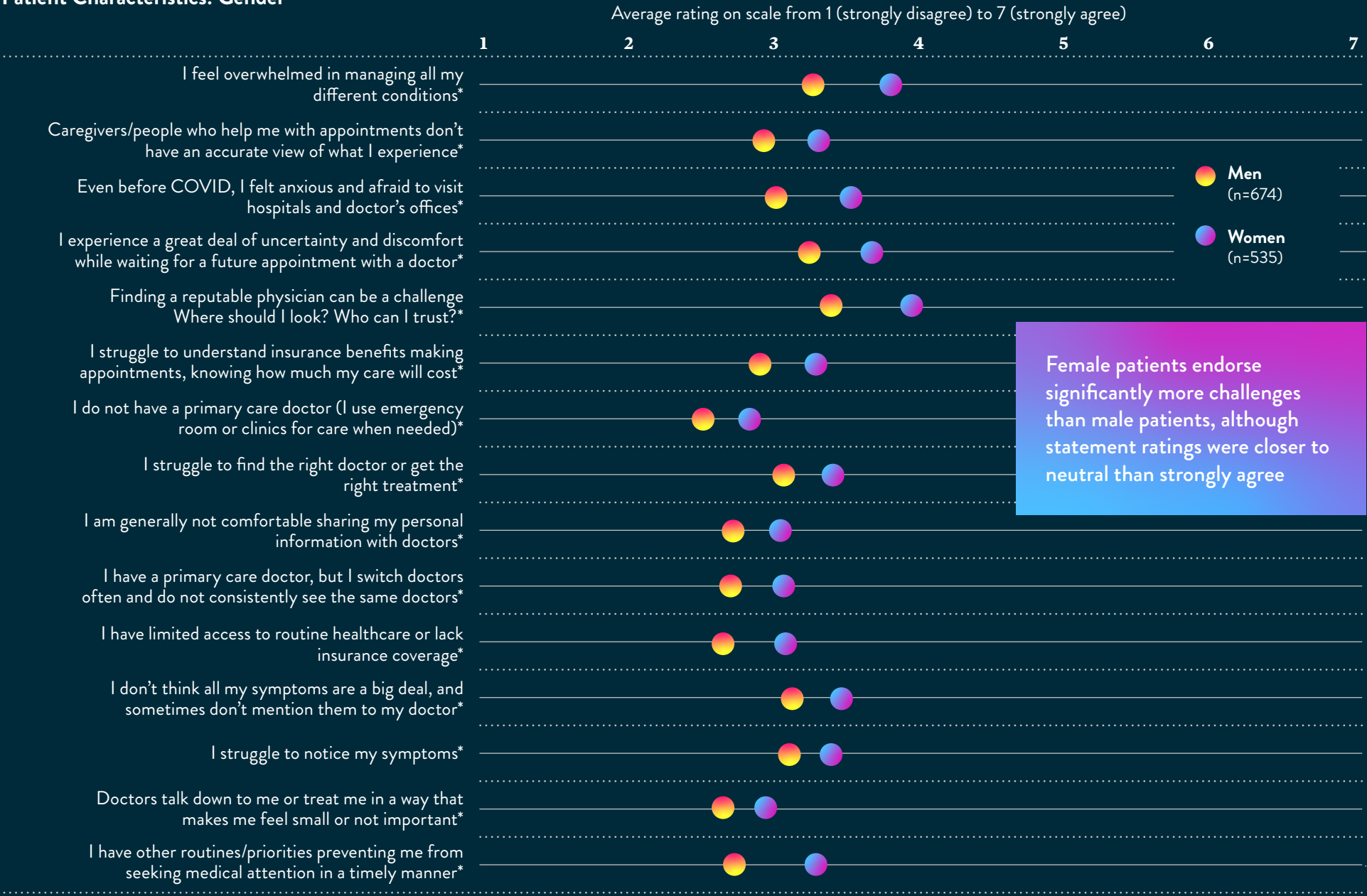
“Chest pain has been traditionally classified as ‘typical’ when it is more likely associated with a heart attack presentation; and ‘atypical’ when symptoms are not manifested primarily as chest pain; patients may use other terminology that could still be related to a heart attack. Unfortunately, the term ‘atypical’ has been more linked to non-cardiac symptoms in origin and this has led to miss-diagnosing coronary artery disease presentations mostly in women that are known to have ‘atypical’ presentations compared to the male population” explained Dr. Natalia Pinilla, Interventional Cardiologist at Hamilton Health Sciences/Niagara Health and Assistant Professor in the McMaster University Department of Medicine. “As a result, women's heart related presentations are not triaged to have appropriate and timely diagnostic work up; determining higher morbidity, mortality; and worse prognosis overall. Due to this misconception the term ‘atypical chest pain’ has been discouraged by the recently published 2021 American Heart Association Guidelines.” Diagnosis comes from a constructive discussion and appropriate communication with our patients; physicians should have the skill to translate patients complaints into the right diagnosis and cardiac testing work up.”

When women's presentations are unrecognized or misdiagnosed – which has long been the case with CMD, previously dubbed as the ambiguous “Syndrome X,” their frustration with the healthcare system grows. In the Beyond Intervention 2021 research, only 44% of women and men with CAD reported favorability with their patient experience, compared with 52% of physicians and 64% of healthcare leaders that felt the patient experience for CAD patients was ideal.<sup>8</sup> Such a disconnect is at best concerning or at worse reflective of a gap between patients' and providers' viewpoints.

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Patient Characteristics: Gender



\*Indicates a statistically significant difference between group means at 90% CI.

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## Underrepresentation of Women and Minorities in Clinical Trials

The results of clinical trials play a large role in determining national clinical guidelines governing how physicians respond to and treat medical conditions. Recent research, however, reveals systemic underrepresentation of both women and minority populations in clinical trials.<sup>2</sup>

This is especially marked for cardiovascular health: although heart disease is the leading cause of death for women in the United States, women account for only 38% of participants in cardiovascular clinical trials<sup>2</sup> despite representing about 50.5% of the U.S. population.<sup>9</sup>

When accounting for prevalence rates amongst Black American women, underrepresentation is an even more stark problem. Black Americans accounted for only 2.9% of participants in clinical pharmaceutical drug trials between 2006 and 2020,<sup>10</sup> despite representing about 14% of the U.S. population,<sup>11</sup> and whose age-adjusted rate of heart disease is 72% higher than for white women.<sup>12</sup>

The EAPCI consensus document acknowledges the gaps in the current study landscape in understanding the full picture of INOCA, including few large studies on the prevalence, pathophysiology, diagnostic approaches, and tailored therapy for INOCA, among other gaps.<sup>3</sup>

Unfortunately, underrepresentation also persists for women leading research investigations, who tend to receive less grant funding. When analyzing National Institute of Health grant renewals, there appears to be a gender bias that leads to gender gaps in grant funding connected to less favorable assessments of women as principal investigators versus

the quality of their proposed research.<sup>13</sup> If women are unable to lead research and provide more equitable recruitment criteria for clinical studies, underrepresentation is likely to persist.

## From Underrepresentation in Clinical Trials to Poor Outcomes in Clinical Practice

Conscious or unconscious gender, racial and ethnic physician bias is seen as a contributing factor to the underdiagnosis, under-referral, and undertreatment of women with CAD.<sup>1</sup>

In a recent editorial, in all studies of Ischemic Heart Disease, women frequently do not receive correct diagnoses and are treated less or less completely according to evidence-based guidelines. Thus, the bias component of management remains a potentially remediable component of adverse outcomes for women.<sup>14</sup>

Such physician bias can be compounded for diseases like INOCA, CMD, and other microvascular issues, which are more prevalent in women than men, where diagnostic guidelines are relatively new, access to proper diagnostic equipment is limited, and there is no medical therapy specifically indicated for the treatment of these diseases.<sup>15</sup> Particularly when it comes to INOCA, incorrect diagnoses can lead to patients being dismissed as “false positives” and not prescribed appropriate medical therapy, which has been proven to improve angina control and quality of life for patients at 6 months and 1 year, as well as risk factor profiles.<sup>16</sup>

“Inherent biases can hinder a physician’s ability to detect and recognize symptoms, especially for populations that have been historically misdiagnosed in the cardiovascular disease setting; such as young, female and certain ethnicities,” said Dr. Pinilla-Echeverri.

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Some data appear to bear this out: a study of heart attack patients in Florida indicated improved survival for women who were managed by a female physician – although whether these data can be extrapolated to all forms of cardiovascular treatments and care settings has yet to be proven.<sup>17</sup>

The intersectionality of poor clinical outcomes for younger patients and women was originally brought to life over two decades ago in a *New England Journal of Medicine* article that found overall mortality rate during hospitalization for myocardial infarction was 16.7% among women and 11.5% among men. When looking at patients under 50 years of age, the mortality rate for women was two times that of men.<sup>18</sup>

## The Financial Impact of Gender Bias in Cardiovascular Care – And Resulting Innovation

When any form of bias contributes to a patient's symptoms being dismissed or overlooked, and physicians do not prescribe guideline-directed therapies, the economic impact on patients – and the overall economy – can be significant.

According to one study, in a single year, the incremental total medical costs per U.S. patient with angina/chest pain were \$14,796, with incremental cardiovascular-specific costs of \$10,949.<sup>19</sup>

Schumann et al. recently published long-awaited functional and economic data for U.S. patients with INOCA symptoms: estimated annual costs per patient were \$9,819 due to absenteeism (patients unable to go to work) and \$4,158 due to presenteeism (patients with

productivity loss at work), for a total per-patient annual cost of \$13,977. When this economic impact is applied across the estimated 1.5 million patients with INOCA in the U.S. workforce, the total estimated annual cost due to productivity loss from INOCA could be as high as \$21 billion per year.<sup>4</sup>

With female prevalence for INOCA ranging from 50-70%,<sup>3</sup> these per-patient annual costs can result in an estimated total cost due to productivity loss of \$10.5-\$14.7 billion for women alone.

Given the high economic burden of these diseases, the social and health ecosystem is ripe for technological innovations that can either help with early prevention and/or detection or with ongoing disease management in ways that can empower patients to take their health into their own hands – a potential avenue where MedTech can help. While women are more likely to suffer negative clinical and economic consequences due to underdiagnosis or undertreatment, they are also 75% more likely to use digital tools to track their health, often as a consequence of exactly these adverse experiences.<sup>20</sup>

Unfortunately, venture capital investments have yet to capitalize on this opportunity, with FemTech companies only accounting for 1.8% of total digital health investments (\$254 million compared to the total annual investment of \$14.5 billion in 2020).<sup>21</sup>

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## The Solution Begins with Conscious Inclusion

To improve population health, the overall quality of care for vascular patients, and to reduce costs – thereby delivering on the “Triple Aim” ideals – the medical community can take measures to reduce bias by becoming more inclusive in clinical trials, data modeling, and investments.

Addressing the lack of trust, lack of access, lack of understanding and lack of a common language in clinical trials can help to reduce the gender and race gaps. Abbott is working to actively increase diversity in clinical trials through: recruitment of patients that are more representative of disease prevalence, support of physicians who practice in underserved communities, and reduce other clinical trial participation barriers by providing transportation and multilingual services.<sup>23</sup>

As healthcare becomes more data-enabled, it will be important for health researchers and practitioners to be cognizant of their own biases, that may, in turn, affect any tools, including AI algorithms, that may be used to help diagnose and treat CAD and PAD patients. With additional digital health tools and screening technologies, computer-aided review of data can help eliminate some of these physician biases that currently result in poorer outcomes for women and people of color, but only if those tools and technologies are truly programmed with diverse data sets that are representative of all populations.<sup>24</sup>

“There are any number of ways that AI-based algorithms can, at their core, have bias,” explains Dr. David G. Armstrong, Professor of Surgery and Director of the Limb Preservation Program for the Keck School of Medicine at the University of Southern California. “We’re trying to

develop broad-based algorithms to allow deep learning instead of just being superficial and focusing on just one skin color. And we’re starting to see the results.”

As the number of women at the forefront of digital research continues to grow, it’s important to recognize that FemTech is not a “side project.” Women who feel they have been failed by clinicians are taking control of their own conditions and treatment options, developing lucrative businesses that can fill a much-needed gap in women’s health.

“By not investing in female-focused tech solutions the industry is missing out on some really big business opportunities,” says Marija Butkovic, LLM, Founder/CEO of Women of Wearables and Forbes Contributor, HealthTech and FemTech. “MassChallenge and BCG research has shown that ROI on investing in women-owned startups is equal, if not higher, than when investing in male founders.<sup>22</sup> With the rise of FemTech, we finally have a great opportunity to invest in a massive gender data gap that exists, as the data currently being collected by FemTech apps, products and platforms could finally start to address this data void.”

“The first step is to recognize physician and cultural bias in cardiovascular care and its socioeconomic and clinical impacts; only then can we begin to outline the necessary steps that must be taken to address the systemic issues underpinning underrepresentation, health inequity and ethnic/sex bias that are currently affecting patients suffering from vascular disease,” says Dr. Nick West, Chief Medical Officer and Divisional Vice President of Medical Affairs, Abbott’s Vascular Business.

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