Cleerly Manifesto for a New Standard of Cardiovascular Care

How healthcare can transition from reactive to tech-enabled preventive cardiovascular care – saving money and lives

Executive Summary

Cardiovascular care today treats the symptoms of disease but not the actual disease. This is the wrong approach – half of patients who have a heart attack don't even show symptoms – and it leads to the dramatic waste and inefficiency that healthcare and patients can ill afford. A new standard of care, emphasizing routine scanning of arterial plaque coupled with a holistic approach to heart attack prevention, is poised to dramatically change the way we approach heart health. Implementing and scaling this new standard of care is not without its challenges, but the potential clinical and financial impacts – and above all, the lives saved – cannot be ignored.

Today's approach to cardiovascular care is unsustainable

Heart disease is the leading cause of death in the United States. According to the CDC, heart disease killed nearly 700,00 Americans in 2020. That's twice the number of people who died from COVID-19, and it exceeds the population of Washington, D.C.[1]

Sadly, many of these deaths are preventable. A buildup of arterial plaque – deposits of fat, cholesterol, and other materials that inhibit blood flow – is what causes a heart attack. It takes decades for this buildup, also known as atherosclerosis, to accumulate. Many preventive measures can be taken to stop it from happening, and these measures are far less invasive, risky, and costly than stent implantation or bypass surgery to remove blockages in the arteries.

Unfortunately, the current standard of cardiovascular care doesn't call for routine measurement of arterial plaque – even though the same imaging technology is used in routine screenings for breast, colon, and lung cancer. Instead of looking at the *causes* of heart disease, we look at its *symptoms*, primarily cholesterol, blood pressure, and body weight. Atherosclerosis is all that matters.

This approach is reactive, not preventive, and it has far-reaching consequences. We all know someone who looked to be the picture of perfect health – balanced diet, active lifestyle, healthy habits – but then suddenly had a heart attack. Half of patients who have a heart attack show no symptoms before the event. Half of patients who die from their first heart attack are younger than 50. And 70% of patients who have a heart attack are considered "low risk" by traditional measures.

The reactive approach to cardiovascular care also contributes to massive waste and inefficiency within the healthcare system. By looking for the symptoms of heart disease first, we are looking in the wrong direction. We're also using the wrong tools: Approximately 70% of referrals to catheterization laboratories are unnecessary (with each test costing roughly $10,000), as are nearly 80% of patient visits to cardiology (each of which comes with an average bill of $7,500); up to 95% of stress tests come back

[1] Leading Causes of Death. National Center for Health Statistics. Last reviewed Jan. 13, 2022.

normal, too. All told, the United States currently spends more than $320 billion annually on cardiovascular care, and this is projected to approach $820 billion by 2030.[2] And patients and their families pay a steep price, too, in the form of income loss, medical bankruptcy, home foreclosure, and a steep increase in annual health insurance premiums.

Clearly, this is unsustainable. Simply put, healthcare must shift its approach from treating symptoms to identifying and preventing heart disease in the first place. This will better capture patients at risk, enable personalized preventive treatment, and improve clinical outcomes while yielding significant cost savings. To accomplish this, we must replace the status quo with a new standard of care: Routine analysis of plaque buildup, coupled with preventive care based in primary care and family medicine.

Negative Clinical Outcomes ● 50% of patients who have a heart attack show no symptoms ● 50% of patients who die from their first heart attack are under 50 ● 70% of patients who have a heart attack are considered "low risk"
Inefficient Clinical Operations ● 70% of cath lab referrals are unnecessary ● 80% of cardiology appointments are unnecessary ● 95% of stress tests come back with normal results

The Far-Reaching Consequences of Substandard Cardiovascular Care

The standard of care remains firmly in place

Will this be easy? No. Several obstacles stand in the way – all of them tied to the current way we practice healthcare.

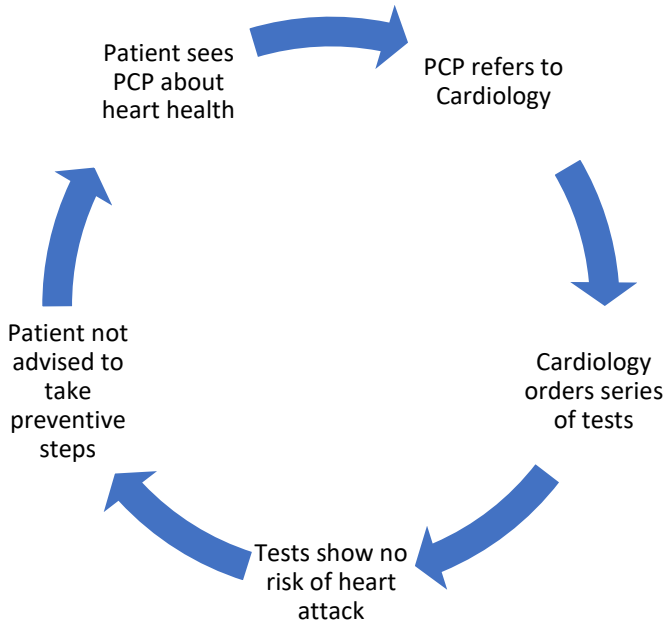
- With 97% of physicians in the United States still relying on fee-for-service (FFS) reimbursement models for their compensation,[3] there's little incentive to adopt standards of care that redirect utilization.
- The care experience is quite fragmented. Most patients begin the heart health conversation with their primary care physician, who refers them to cardiology. Then, the cardiologist runs a series of services (EKG, ultrasound, and/or stress test) that can be high-cost and less effective.
- Radiologists are often left out of the heart health conversation despite clinical guidelines from the American Heart Association and the American College of Cardiology that increasingly recommend non-invasive coronary computed tomography angiography (CCTA) for heart disease prevention, as CT scans can measure arterial plaque.
- Because the cardiovascular care experience is fragmented, there is no single decision-maker within a health system or health insurer who can move the needle on modernizing heart health and advocate for investment in prevention.

[2] Heart Disease and Stroke Cost America Nearly $1 Billion a Day in Medical Costs, Lost Productivity. Centers for Disease Control and Prevention Foundation. April 29, 2015.

[3] Equipping physicians for value-based care. Deloitte. Oct. 14, 2020.

- Only about 4 in 10 patients discuss heart health with their physicians. That has led to limited awareness of the true cause of heart disease, as only 1 in 4 Americans know the role of arterial plaque in causing a heart attack.[4]
- Cloud-based systems for administering CT scans, analyzing results, and providing physicians with a recommended course of action are available today but face resistance for two key reasons: Their use is inconsistent with the traditional infrastructure model of on-premises PACS systems, while physicians have been told that artificial intelligence (AI) will make them "obsolete."[5]

Changing the standard of cardiovascular care won't be easy – but it's not impossible. Cleerly is here to help.

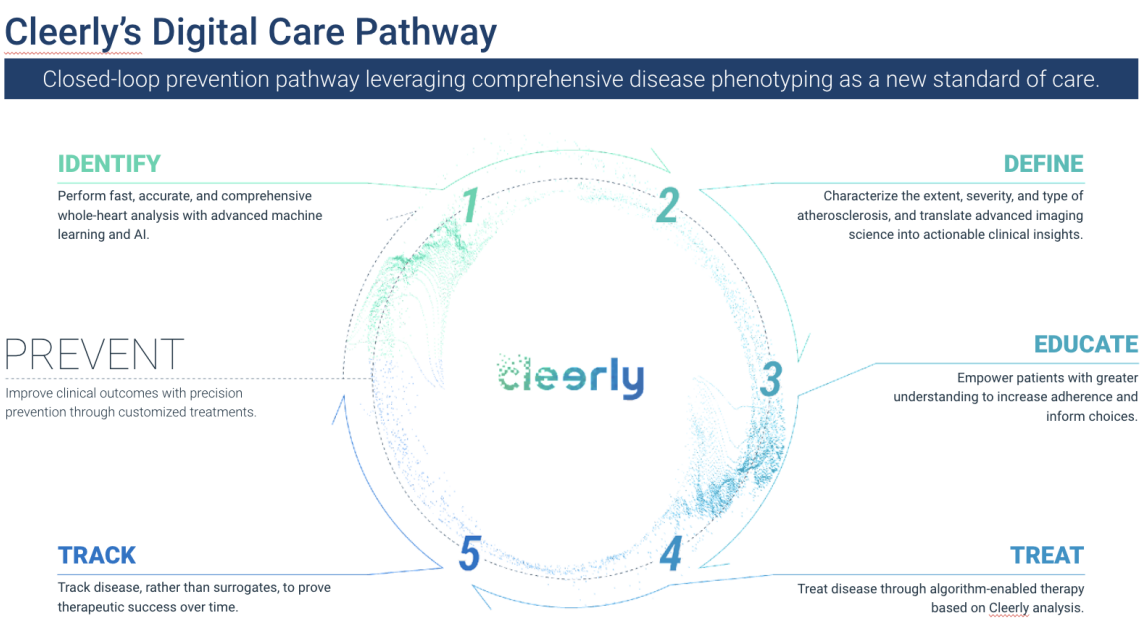


The Standard Workflow in Cardiovascular Care

How Cleerly plans to change cardiovascular care

Cleerly has developed a digital care platform to help physicians precisely identify, define, and treat heart disease earlier. Cleerly measures the underlying cause of heart disease – atherosclerosis – instead of its indirect markers like cholesterol or blood pressure. The Cleerly platform offers simple, fast, and accurate heart disease diagnostics and reporting that can be personalized to individual stakeholders – be they radiologists, cardiologists, primary care physicians, or patients and their caregivers. With personalized reporting, physicians can provide preventive treatment plans throughout the patients' continuum of care, improving clinical outcomes while drastically reducing the cost of cardiovascular care.

[4] National Study Finds Americans Don't Know the Facts or Their Risk for Heart Disease. MDVIP. Jan. 31, 2019.
[5] Could artificial intelligence make doctors obsolete? BMJ. Nov. 7, 2018.



Cleerly believes that the new standard for cardiovascular care should be routine CCTA screening for atherosclerosis in community-based imaging centers. If patients undergo routine screening for common cancers, then the same should be true for heart disease – the No. 1 cause of death in the United States. There are currently 10 million coronary imaging tests performed in the United States each year, primarily on patients deemed to be high risk. Wider use of CCTA technology could increase this number to 100 million scans per year, making it possible for providers to routinely scan the 48% of American adults who have some type of cardiovascular disease.[6]

Critically, this new standard of cardiovascular care aligns with both traditional fee-for-service medicine and value-based care models. Providers reimbursed under FFS models will increase patient volume from CCTA scans of at-risk patients who are otherwise asymptomatic (i.e., normal cholesterol, blood pressure, or body weight), along with downstream revenue from preventive services to reduce heart attack risk, ranging from lifestyle interventions to prescription medications. Meanwhile, providers in value-based care arrangements will reduce financial and operational waste by providing more appropriate cardiac care and increase reimbursements tied to improved clinical outcomes.

The 5 steps that will make this change happen

We recognize that changing the current standard of cardiovascular care – which has been taught in medical school and practiced in a clinical setting for several decades now – is a significant undertaking. It takes a village, as the saying goes. There are five key strategies for making this happen.

Empower primary care. Right now, primary care and family health physicians refer nearly all heart health questions to cardiology. Providing these physicians with comprehensive coronary analysis,

[6] Cardiovascular diseases affect nearly half of American adults, statistics show. American Heart Association. Jan. 31, 2019.

reporting, decision support, and educational resources at the point of care will empower them to deliver a more appropriate level of treatment given a patient's individualized heart attack risk. Instead of providing reactive treatment after a heart attack, physicians can offer longitudinal and proactive treatment that prevents a heart attack from even happening. This vastly improves clinical outcomes, significantly reduces utilization of high-cost and invasive testing procedures, and it puts the heart health conversation in the hands of the physician that patients are most likely to know and trust. It also shows physicians that artificial intelligence and cloud-based applications can be trusted instead of feared.

Partner with health systems. No one achieves change in healthcare alone. Working alongside health systems makes it possible to demonstrate how quickly they achieve ROI with routine CCTA scanning in place – especially when it's available at imaging centers within patients' communities. What's more, CCTA scanning and analysis can now become part of the ongoing conversation with patients about preventive care, just like the mammogram or colonoscopy for cancer prevention. This makes it possible for radiology, cardiology, primary care, and health system leadership to come together and take a holistic approach to heart health. Instead of waiting until patients need a stent or bypass, an approach that emphasizes risk identification, quantification, and preventative care leads to better clinical outcomes and happier, healthier patients.

Optimize clinical workflows. As we work to create a new standard for cardiovascular care, we must consider clinical workflows in two ways. One is how clinical staff work at the point of care. Clinicians have been burned before by technology that has over-promised on efficiency gains, so we must be careful to embed our tools where they are already working. Forcing extra clicks will only lead to frustration and lax adoption. The other consideration is the workflow of cardiovascular care itself. Most attempts to "fix" the problem simply plug new tools for patient identification or data analysis into the existing care workflow. But that workflow is broken. That's why a new standard of care demands a new end-to-end clinical workflow that makes it easy for patients to get the CCTA scans and preventive services they need while deprioritizing the expensive, invasive services they don't. When we address both concerns at the same time – making the new standard of care accessible where and when clinicians need it – then we ease the transition from the old way of doing things.

Generate evidence. Speaking of the old way of doing things, it's no secret that healthcare takes time – 17 years, roughly[7] – to adopt new practices or treatments. The best way to combat this time lag is to continually generate evidence to drive change. Our push for a new standard of cardiovascular care comes after more than a decade of clinical trials that have shown the ability to depict high-risk arterial plaque in 58% more patients, reduce referrals for invasive coronary angiography by up to 77%, and detect heart disease in up to 75% more patients. Meanwhile, ongoing clinical trials are focused TO COME. This all builds to the most important evidence that this new standard of care can generate: A CCTA scan that shows a patient the presence of arterial plaque that would otherwise never be detected.

Educate providers and patients. Education is a critical step in making the case for a new standard of cardiovascular care. For decades, the heart health conversation has focused on factors like cholesterol, blood pressure, and weight. Those are important for overall health, but they simply aren't the underlying cause of heart disease. Patients need to know what arterial plaque is, what their risk of heart

[7] The answer is 17 years, what is the question: understanding time lags in translational research. *Journal of the Royal Society of Medicine*. December 2011.

disease is, and steps they can take to prevent a future heart attack. Similarly, the mindset in primary and family care needs to shift toward prevention and away from unnecessary testing and invasive treatment. To make this happen, physicians need the right tools to have heart health conversations in real time with their patients – tools that they lack under the current standard of care.

Let's redefine the standard of cardiovascular care

We've spent a lot of time presenting statistics to make our case for a new standard of cardiovascular care. There's one we haven't mentioned. The number of people who die from heart disease in the United States every day is the equivalent of nine fully loaded 737s crashing and killing everyone on board. If nine passenger planes crash every day, there would be national outrage. Why don't we feel the same way about heart disease?

The way we currently approach cardiovascular care suggests that we have simply accepted this death toll as a way of life. We've accepted that we're going to lose nine planeloads of Americans to heart disease every day. We've accepted that it's OK to lose parents, spouses, siblings, children, friends, mentors, colleagues, and others we love, look up to, and draw inspiration from. We've accepted heart attacks as a public health epidemic – and an entirely preventable one at that.

It's time to redefine the standard of care for heart health. CCTA should be the standard screening tool for coronary heart disease worldwide. It should be readily available in the communities where patients live and work. Physicians should be as ready, willing, and able to recommend it as they are the colonoscopy, mammogram, and low-dose lung CT – and they should have the right tools at the point of care to help patients make the right decisions to prevent a heart attack from ever happening.

Join us in transforming heart health

In this manifesto, we have discussed why the current standard of cardiovascular care leads to waste, inefficiency – and hundreds of thousands of preventable deaths every year. We believe a new standard of care is possible using existing technology and rethinking how we measure heart health and treat the cause of heart disease instead of its symptoms. We recognize that healthcare's status quo stands in our way, but we also know that the benefits are too great to ignore. We look forward to a new standard of cardiovascular care that emphasizes routine and accessible screening, coupled with a holistic and preventive approach to heart health – and we hope you will join us on this journey.

Learn more about Cleerly by visiting our website or sending us an email.