Abbott's Beyond Intervention – Reimagining Patient Care

300 million life-years have already been lost to cardiovascular disease.[2] We, as a society, are at an inflection point in the treatment of vascular disease. New technologies and opportunities for data-driven insights are being developed and adopted by healthcare providers.

Abbott's Beyond Intervention Research addresses the demands of today's diverse patient care landscape and new approaches on the horizon. It explores the differing perceptions of over 3,300 global citizens from 14 different countries, including 2,250 people suffering from vascular diseases (including Peripheral Artery Disease and Coronary Artery Disease), 753 physicians, and 299 healthcare leaders.

It's time we reimagine patient care.

Visit us at **www.cardiovascular.abbott/us/en/campaigns/beyond-intervention** to download our latest research.

CASE STUDY:

How One IDN is Using OCT Technology and Standardized Workflows to Optimize Cardiovascular Care

CARDIOVASCULAR DISEASE (CVD) IS CURRENTLY THE LEADING CAUSE OF DEATH WORLDWIDE, CLAIMING 18 MILLION LIVES ANNUALLY.[1]

With the rapidly aging population (by 2050, 1 in 6 people will be age 65 or older[2]) and the explosion of CVD and its risk factors in low to middle income countries, CVD shows no signs of slowing down.[3] Age, race, ethnicity or sex should not put people at a higher risk for CVD but, unfortunately, each of these factors has an impact. These differences not only affect your prospects for having CVD, they also help determine your chance of survival.[4]

The growth of CVD worldwide coupled with health system and socio-economic challenges have brought us to a crucial point where technologies and physician practices need to innovate and evolve to effectively meet the needs of the growing CVD population. Enter Abbott's OCT (optical coherence tomography) Technology, their LightLab Clinical Initiative, and an Integrated Delivery Network (IDN) in the southwest region of the United States.

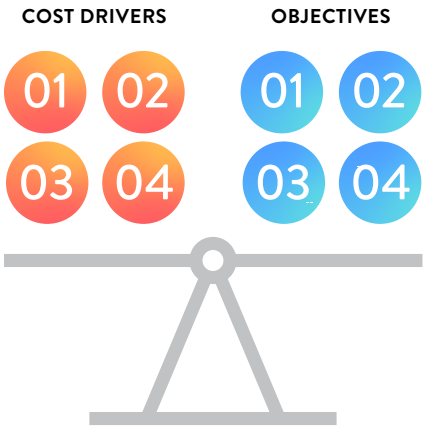
REINVENTING THEIR CATH LABS

A non-profit, local community healthcare system serving 1.6 million people encompassing six acute-care hospitals, an extensive medical group, outpatient

See Important Safety Information referenced within.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

Healthcare leader dilemma



Cost Drivers:

01 Fragmented teams and communications
02 Poor procedural outcomes
03 Disjointed data streams
04 Diminished patient experiences

Objectives:

01 Driving new revenue streams
02 Implementing cost savings programs
03 Integrating new technologies and procedures
04 Improve patient experience and outcomes

surgery centers, a cancer care network, clinical research, medical education, a foundation, and community services with approximately 12,800 employees, 3,500 affiliated providers and 3,100 volunteers was looking to reevaluate their imaging technologies.

In early 2019, Stuart Scherger, Senior Director Clinical Systems at the IDN, led a team of stakeholders to review available intravascular imaging technologies. Like most health system administrators, Mr. Scherger and his team were looking to drive new revenue streams, implement cost savings programs and integrate new technologies and procedures that would improve patient experience and outcomes. The problem was determining what technology would best help them move the needle on these challenges.

"With these devices there are fads, things come and go," says Mr. Scherger. "The capital outlays are significant, especially when you're multiplying it by many hospitals or departments. We had to be very sure that this was worthwhile to invest in and would have traction beyond some of these short-lived products that are around for a couple of years. We read the literature, the background and looked at the differentiation between what is out there. Abbott's OCT is a standalone technology which is different than other intracoronary diagnostic devices and it was a compelling enough story to bring it into our health system for our patients."

Dr. Bimal Padaliya, an Interventional Cardiologist, was recruited to drive the intravascular imaging program at the IDN. During Dr. Padaliya's interventional cardiology fellowship, he had the opportunity to utilize and become proficient with intracoronary imaging and specifically OCT, relatively newer technologies in use in Percutaneous Coronary Intervention (PCI) treatment of diseased arteries.

OCT is a type of advanced medical imaging that uses light waves to take near-photographic quality cross-section pictures of living tissue. During PCI procedures, OCT imaging is used to take detailed images of the interior of blood vessel walls. These images are used to help determine the extent and burden of atherosclerotic plaques (build-up of cholesterol, calcium, and other organic material) in arteries. This detailed understanding helps an interventional cardiologist determine whether a stent is needed to treat a blockage, guide a stent placement during a procedure, and determine the stent optimizations post-placement.

When Dr. Padaliya joined the IDN, they had the technology to use OCT but it wasn't being optimized. Changing that landscape presented an exciting challenge.

See Important Safety Information referenced within.

Structure of the LightLab program

1 BASELINE PHASE

Assessment of current practice and collection of data for comparison to future phases

2 CLINICAL ACCURACY

Adoption of LightLab OCT-focused workflow and the effect on accuracy/precision

3 WORKFLOW UTILIZATION

Standardization of LightLab OCT-focused workflow and its effect on efficiency

4 WORKFLOW OPTIMIZATION

Optimization of workflow to reduce angiographic pre-diagnosis steps and improve efficiency

> The capacity, the device and how it's different. You can see the team actually light up, no pun intended, with the word LightLab. But the team is actually excited, and they say 'wow, this is different. Why wouldn't we want to use this?' Personally, I would want this for my parents, my grandparents, my neighbor. It's a whole new world. It's not giving orders. It's about sitting down to the table, talking through the scenarios, having real, constructive conversations and driving towards the outcome. The patient can see it is different too. For me, that is what matters."
>
> – Mr. Stuart Scherger
> Sr. Director Clinical Systems

THE LIGHTLAB CLINICAL INITIATIVE

The LightLab Clinical Initiative was developed by Abbott to improve cath lab workflow, safety, and efficiency via standardized use of the full range of information derived from OCT. The initiative was a multi-phase program developed to examine the role and impact of OCT use and consisted of implementing the standardized workflow and OCT technology in 12 centers in the United States with prospective PCI procedural data collected by trained field clinical specialists embedded at these sites.

The IDN's participation in LightLab included using OCT technology and a standardized workflow for 230 cases to inform pre-treatment diagnosis and assessment, facilitate treatment guidance and decision-making, and optimize post-treatment analysis.

"Being a LightLab site lead was a great opportunity for me. I assumed everyone knew what OCT was and everyone was using it because that's how I was trained. This wasn't exactly the case as OCT is perceived to be a luxury technology," says Dr. Padaliya. "Operating a cath lab is really a team sport. You're only going to be as good as the weakest link. If the staff doesn't know what you're thinking, you're already at a disadvantage. One of the things that helped make it easier to teach and learn is having a workflow process, like the one leveraged in LightLab. You first look at X, then you look at Y, then you do Z. Changing the culture a little bit can be somewhat tricky but you can be successful when you have projects like LightLab that are supported by industry. At the end, this can only be for the betterment of the patient."

According to Dr. Padaliya, the biggest differentiator of OCT and LightLab is the standardized MLD MAX workflow.

From a healthcare leader perspective, Mr. Scherger was quick to point out that sometimes getting a team to adopt new technologies is slow and cumbersome. This becomes a waste of capital expense if the health system invests in something that goes unused. Not the case with OCT. Because of the simplicity, structure of the workflow and the support of Abbott, his team was onboard from the start.

THE RESULTS

Data from this IDN showed that LightLab enabled physicians to quickly adopt the use of OCT technology and immediately make an impact on patient's diagnosis, treatment, and overall satisfaction.

Results:

- Impacted decision-making in 97.6% of cases because of OCT
- Significant reduction in contrast volume
  - Medians: 148 cc for angio-guided PCI and 106 cc for LL OCT workflow-guided PCI, p = 0.01

See Important Safety Information referenced within.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

OCT Technology has further evolved! Ultreon™ 1.0 with Artificial Intelligence is the latest evolution in OCT Technology

Streamlined and intuitive, Ultreon™ 1.0 software provides even better insights to optimize patient outcomes through automation and an improved workflow.

1 **Allows interventional cardiologists to see inside the heart** during PCI and gain additional insights

2 **Guides physicians through PCI step-by-step** following MLD MAX workflow and provides insights on morphology, vessel sizing, stent placement and post-stent optimization for more accurate decision-making

3 **Powered by artificial intelligence (AI)** that enables automatic quantification of calcification and vessel sizing

- **Significant reduction in radiation exposure**
  - Medians: 1517 mGy for angio-guided PCI and 920 mGy for LL OCT workflow-guided PCI, p = 0.01
- **Significant reduction in variability for procedure time**
  - Standard deviation comparisons:
    - Overall procedure time: 46 mins for angio-guided PCI and 20 mins for LL OCT workflow-guided PCI, p < 0.01
    - Diagnostic procedure time: 15 mins for angio-guided PCI and 6 mins for LL OCT workflow-guided PCI, p < 0.01
- **Significant reduction in variability for contrast volume, fluoro time and radiation exposure**
  - Standard deviation comparisons:
    - Contrast: 102 cc for angio-guided PCI and 47 cc for LL OCT workflow-guided PCI, p < 0.01
    - Fluoro time: 26 mins for angio-guided PCI and 8 mins for LL OCT workflow-guided PCI, p < 0.01
    - Radiation exposure: 1565 mGy for angio-guided PCI and 952 mGy for LL OCT workflow-guided PCI, p < 0.01
- **Reduction of malapposition and under-expansion of stents, and thus the need for additional optimization**

TODAY, THIS IDN HAS FULLY ADOPTED THE OCT TECHNOLOGY AND STANDARDIZED WORKFLOWS.

According to Mr. Scherger, adopting OCT technology has impacted his health system beyond the cath lab and, from a patient experience perspective, is a success.

"Once you move past the initial concerns over startup and cost and training, the support provided by Abbott is noteworthy. That training that's given to the medical staff and clinical staff was an incredible value add, and all of that is realized in a very short term and the information you're getting back provides safe, efficient care with really great outcomes for the patients. And our patient satisfaction scores are reflective of that," says Mr. Scherger.

Mr. Scherger continues, "It's important that healthcare organizations view the patient care continuum as an experience rather than just a journey. We are in the business of providing optimal patient experiences and OCT is a big piece of providing that."

After the success of LightLab, Abbott developed the Imaging Partnership Program (IPP) to provide similar full-time Abbott support for health systems looking to drive competency amongst their cath lab teams when implementing and utilizing its OCT technology. For more information about Abbott's Beyond Intervention research, visit **www.cardiovascular.abbott**.

See Important Safety Information referenced within.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

IMPORTANT SAFETY INFORMATION

℞ ONLY

OPTIS™ Next Imaging Systems and Software

INDICATIONS

The Ultreon™ 1.0 Software is intended to be used only with compatible OPTIS™ Next Imaging Systems. The OPTIS™ Next Imaging System with a compatible Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly™ OPTIS™ Imaging Catheter or Dragonfly OpStar™ Imaging Catheter is not intended for use in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure. The OPTIS™ Next Imaging System is intended for use in the catheterization and related cardiovascular specialty laboratories and will further compute and display various physiological parameters based on the output from one or more electrodes, transducers, or measuring devices. The physician may use the acquired physiological parameters, along with knowledge of patient history, medical expertise, and clinical judgment to determine if therapeutic intervention is indicated.

CONTRAINDICATIONS

Use of the Ultreon™ 1.0 Software is contraindicated where introduction of any catheter would constitute a threat to patient safety.

Contraindications include:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for coronary artery bypass graft (CABG) surgery
- Patients disqualified for percutaneous transluminal coronary angioplasty (PTCA)
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure
- Inability to tolerate systemic anticoagulation is a contraindication to use of OCT for coronary imaging.
- PressureWire™ Guidewire is contraindicated for use in the cerebral vasculature.
- The system has no patient alarm functions. Do not use for cardiac monitoring.

COMPLICATIONS

The risks involved in vascular imaging include those associated with all catheterization procedures. The following complications may occur as a consequence of intravascular imaging and may necessitate additional medical treatment including surgical intervention.

- Abnormal heart rhythm or arrhythmias
- Acute myocardial infarction
- Allergic reaction to the contrast media or drug administered for the procedure
- Arterial dissection, injury, or perforation
- Bleeding
- Catheter access site reactions: sterile inflammation or granuloma
- Coronary artery spasm
- Death
- Embolism
- Myocardial ischemia
- Renal insufficiency or failure from contrast media use
- Repeat revascularization
- Thrombus formation, abrupt closure, or total occlusion
- Tissue necrosis
- Unstable angina
- Hypotension

WARNINGS

- Refer to the contrast media Instructions for Use for general warnings and precautions relating to use of contrast media.
- The heart rate and mean pressure values shown on the OPTIS™ Next Imaging System are for reference only and are not intended to be used as the primary display.
- The system may place the point of index value at the wrong location due to pressure artifacts, for example: abnormal heartbeats, artifacts in AO (Pa) caused by flushing of guiding catheter, or valve opening / closing. The physician should always confirm that the point selected by the system is a valid point for the calculation of index value.
- Inside the catheterization laboratory, only port-powered USB drives may be connected to the USB port. Connecting externally powered devices to the USB port in the patient vicinity may compromise electrical isolation and cause patient injury.
- To protect the privacy and security of sensitive information, including electronic protected health information (EPHI), and to protect the integrity of the system itself, the system should be located in a physically secure, access-controlled environment. Do not use the OPTIS™ Next Imaging System if there is reason to believe the system's security has been compromised or if the system was unaccounted for during a period of time (i.e., misappropriated, modified, or tampered with).

PRECAUTIONS

- Safety and effectiveness have been established for the following patient population: adult patients undergoing non-emergent percutaneous coronary interventions in lesions with reference vessel diameters between 2.0 to 3.5 mm, which were not located in the left main coronary artery or in a target vessel which has undergone previous bypass procedures.
- Monitor the OCT image for indications of Dragonfly™ Imaging Catheter optical failure. If optical failure is suspected, remove the Dragonfly™ Imaging Catheter from the patient, press "Unload" on the drive motor and optical controller (DOC), detach the catheter, and replace it with a new one.
- If the pullback triggers before contrast is injected, repeat the pullback.
- For optimal imaging, only use 100% contrast media.

1. "Cardiovascular Diseases (CVDs)," World Health Organisation, May 17, 2017.
2. GBD 2017 Causes of Death Collaborators. Global, regional and national age-sex-specific mortality for 282 causes of death in 195 countries and territories, 1980-2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet* 2018; 392: 1736-88.
3. Mensah GA, Roth GA, Fuster V., "The Global Burden of Cardiovascular Diseases and Risk Factors: 2020 and Beyond," *J Am Coll Cardiol* 2019; 74: 2529-31.
4. American Heart Association. "Cardiovascular Disease: A Costly Burden for America - Projections through 2035", American Heart Association CVD Burden Report, 2017, Page 7.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at vascular.eifu.abbott or at medical.abbott/manuals for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use with healthcare professionals only.

Information contained herein for DISTRIBUTION in the U.S. ONLY.

Abbott
3200 Lakeside Dr., Santa Clara, CA 95054 USA, Tel: 1.800.227.9902

www.cardiovascular.abbott

Abbott