# The Time Is Now to Enter the Out-of-Hospital Market

Surveying the current landscape to open a single or multispecialty OBL or ASC.

#### With Pradeep Nair, MD, and Mike Ferguson

he pioneers in office-based labs (OBLs) emerged in the late 2000s, beginning with peripheral procedures. These physicians were the first to experience the significant benefits of providing care in out-of-hospital settings, including autonomy and freedom in their treatment strategies, greater flexibility in work-life balance, and improved patient experiences. By 2019, the number of OBLs expanded, and the Centers for Medicare & Medicaid Services (CMS) authorized 17 cardiac catheterizationrelated procedures in the OBL setting. In 2020, CMS authorized six additional CPT codes for percutaneous coronary intervention (PCI) in ambulatory surgery centers (ASCs). By this time, according to the Outpatient Endovascular and Interventional Society, the number of OBLs had tripled to 700 labs. Furthermore, in 2022, CMS announced new complexity codes applicable to certain cardiac procedures in the ASCs that include "add-on" services for instantaneous wave-Free Ratio (iFR)/fractional flow reserve (FFR) or coronary intravascular ultrasound (IVUS) and noncoronary IVUS procedures. Initially not a forerunner in the ASC market, the momentum of cardiology has accelerated in the last

few years, with 33% of procedures estimated to be performed in the ASC by the mid-2020s.<sup>2</sup> Similar growth is expected in other specialties.

This evolution, alongside external forces from societies and insurers, set the stage for accelerated growth and support for interventional cases moving to the out-of-hospital setting. Thus, more enticing opportunities to open an out-of-hospital lab for entrepreneurial physicians, as well as hospital administrators looking to combat rising costs within the hospital setting, are emerging.

The following discussion highlights the evolving environment and opportunities for opening an out-of-hospital care site, such as an OBL or ASC. Mike Ferguson, President and Cofounder of Horizon Solutions and a 26-year veteran in the OBL/ASC market, has watched the industry emerge and grow and shares his advice on what entrepreneurial physicians can do to capitalize on this growing trend and how to work with management firms and industry partners to maximize success. Dr. Pradeep Nair, interventional cardiologist at Cardiovascular Institute of the South (CIS), also shares his journey and why he believes that "OBLs and ASCs are a good investment."



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## What trends do you see in the out-of-hospital market?

Boston Scientific, and Surmodics.

**Mr. Ferguson:** OBLs remain very popular due to the ease for a single practitioner to open one. However,

we're seeing accelerated growth in hybrid (OBL/ASC) and ASC models, with more multispecialty groups going straight to an ASC model. Cardiology is relatively a latecomer to the ASC space, driven largely by the

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recent positive changes in CMS reimbursement. The approval of PCI in the out-of-hospital market and new complexity codes are responsible for rapid growth in cardiology procedures outside of the hospital. Other specialties including spine, pain management, orthopedics, and gastrointestinal are still growing year-over-year but at a slower rate than cardiovascular. We are also seeing established multispecialty groups pull in cardiology to add value to their ASCs. Even groups that are building cardiology-only ASCs are looking to diversify in related specialties, such as interventional radiology or vascular work. My expectation is that growth will continue.

#### What motivated you to enter the OBL/ASC market?

Dr. Nair: It has been almost a decade since I joined CIS as Dr. Craig Walker's endovascular fellow. Immediately following my interventional cardiology training at the University of Pittsburgh, I performed interventions solely at hospitals with on-site cardiothoracic surgical backup. However, 2 years prior to joining CIS, I was blessed to have an opportunity to work alongside my father, Dr. V. Krishnan Nair, a noninvasive cardiologist. I served as the catheterization laboratory director for a community hospital that did not have on-site surgical backup. In retrospect, I feel this primed me for entering the OBL/ASC market. Now, more states are allowing PCI procedures without on-site surgical backup. However, intervening on unstable patients with acute myocardial infarctions and stable coronary lesions of varied complexity in a nontertiary care facility without surgical backup enhanced my confidence levels tremendously. At the time, I did not realize I was preparing myself for a career in outpatient-based interventions. I truly felt back "home" in the lab when Dr. Walker's dream of establishing our first ASC came to fruition. CIS was started by Dr. Walker 40 years ago as a one-man practice and has grown to 90 physicians and roughly 1,200 employees in 22 facilities. Our practice goal is to provide our patients with the highest-quality cardiovascular care available.

For our group, that means technologic superiority. We have been first-year investigators of many new products. We are committed to developing next-generation leaders, devices, tools, and techniques via research and education. We comport a sense of compassion and respectful patient communication in all endeavors—a quality that seems to be diminishing in health care overall. Hospitals serve a vital role in our communities for treating acutely ill patients. However, over the last several years, many hospitals have become increasingly

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financially driven, and I often hear frustration from colleagues in these systems who have lost the ability to control patient care decisions. Our motivations to open an OBL/ASC were to enhance quality of care and patient satisfaction, retain increased control over care decisions, and improve quality of life for every person in our organization.

### Which model is best: OBL, ASC, or hybrid? Single specialty or multispecialty?

**Dr. Nair:** That decision should ultimately be based on the needs of the community and the physician group. We chose to focus within the cardiology space because our group is large, and we have the volume for a single specialty. We also wanted to 100% focus on cardiology and optimized our operations around this single specialty. CIS was already operating multiple OBLs throughout Louisiana, so we enlisted Philips' assistance with the buildout of our ASC. We came to this decision because we were encountering capacity and scheduling issues at the hospital and lack of control over equipment and staff.

I found the Philips team tremendously helpful in working through the various issues you encounter when building an OBL or an ASC. The rules are different for each and certainly more stringent for an ASC. You must know the rules or you'll end up with cost overruns or worse, reimbursement or delayed permitting issues. We built a 27,000 square foot facility designed to achieve optimal patient satisfaction and outcomes.

Mr. Ferguson: The decision should be driven by market need and referral patterns. You must understand which specialties are needed and which specialties your group can support. A physician group might consider multispecialty up front to diversify risks associated with potential changes in reimbursement. We typically recommend that our clients consider a hybrid OBL/ASC where you can perform OBL procedures 2 or 3 days a week and ASC procedures 2 or 3 days a week. That model provides the greatest flexibility, plus it is more cost-effective to plan for ASC capabilities up front than retrofit an OBL

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building later. Keep in mind, a hybrid model will require more up-front permitting with the state than an OBL, and you can only change it once a year.

Typically, multispecialty ASCs will have two or three procedure rooms and one operating room. They are around 10,000 to 20,000 square feet depending on the number of specialties. If it is an ASC only, physicians will need office space nearby for office hours and then do procedures in the ASC.

# What impacts do you anticipate resulting from the recent CMS changes?

**Mr. Ferguson:** Starting in 2018, and now with the recent approvals by CMS, there has been a significant, positive impact on the growth of cardiology-focused ASCs. This favorable reimbursement environment is going to be the primary driver of growth in cardiology ASC procedures anticipated over the next couple of years. The inclusion of imaging such as IVUS and physiologic measurements such as iFR/FFR is also playing a pivotal role in these procedures and enabling more cardiac patients to utilize the ASC, get in and out quicker, and have that white-glove experience.

This transition of PCIs to the ASC setting will also impact capital equipment purchase requirements. Many interventional cardiologists would prefer to do their PCI procedures on what's called a fixed system versus the mobile unit, typically found in the ASC. That is a big-ticket item, especially for a multispecialty practice interested in adding cardiology. Our industry partner, Philips, offers a rewards program that enables physicians to earn financial rebates for device purchases that can be applied to an equipment loan. This can be a huge benefit to offset capital equipment costs.

On the OBL front, we are seeing a constriction of some reimbursement for peripheral procedures. Management companies can work with their clients to identify costs savings within the practice to offset the reduction or suggest other options such as diversifying the practice or transitioning to a hybrid model to minimize risks.

## How would you describe your experience working with an industry partner?

**Dr. Nair:** It's been spectacular. We sought out Philips for our ASC buildout because we liked their equipment and the SymphonySuite program. They have been very innovative in imaging and have brought many firsts to the field. Their equipment is world-class and reliable. To be fair, we looked at a variety of systems but decided to go with Philips.

The Philips team led the project, and we found them to be very knowledgeable and first rate. I would advise

I would advise any physician looking to enter the OBL/ASC market to seek out an industry partner or management company that is an expert in the model you are pursuing, your specialty or specialties, and your state requirements . . . . Just having a big practice or having expertise in a field does not necessarily make you capable of running an ASC." — Pradeep Nair, MD

any physician looking to enter the OBL/ASC market to seek out an industry partner or management company that is an expert in the model you are pursuing, your specialty or specialties, and your state requirements. When building an OBL/ASC or hybrid-based practice, there are many factors to consider. You need reliable advice that you can count on during the planning phase and the buildout and equipping phases, which represent your largest investment. Likewise, ongoing operations are also important, as this supports your patient-facing processes that you need to get right. Other functions you can have a management company or industry partner support include reception, supplies procurement, coding and billing, finance, and governance setup, including policies and procedures. Just having a big practice or having expertise in a field does not necessarily make you capable of running an ASC. As physicians, we have historically not managed businesses. We see patients and take care of patients. That's what we are trained and paid to do. But if we also want our independence—to set our own schedule, make the calls on patient care, and improve the patient experience—we must learn about business. A knowledgeable partner can help you set realistic expectations, launch a viable business, and enable you to maximize your success.

# What services does Horizon Solutions provide? How do you work with industry partners?

Mr. Ferguson: We can provide a full turnkey process from site selection to buildout to day-to-day operations. The relationship is structured to fit the needs of the physician group. The first step in any project—the most important step—is the development side, and that is where I see a lot of physicians struggle just trying to figure out how to get it off the ground. We do a lot of research and market analysis to determine the ideal location. This is driven by volume and referral patterns. Next, we determine if we can rehab an existing facility

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or if we need to build from the ground up. We pride ourselves on taking care of the hundreds of details along the way and providing weekly updates to the physician. It eliminates a lot of time, energy, and stress for physicians so they can focus on patient care. We also specialize in the regulatory side, making sure that the ASC has both state and CMS approval.

Partners like Philips are very important to the success of Horizon Solutions and our clients. So, we work closely with those who understand the out-of-hospital market. We get Philips involved when we start to design the site, and they are an integral part of the team throughout the development process. Philips has been the leader in this space, and they set a high bar for other industry partners to reach.

## What questions do you frequently hear? What questions should a physician ask?

Mr. Ferguson: The most frequent questions are: What are your thoughts on reimbursement, and what direction is it headed? Should I bring in another physician or another specialty? What's an appropriate timeline to get the infrastructure built out? Who's going to run and/or manage this thing once it's up and running? Do I have to give up ownership of my practice? Those are really the key things, but for us it's an everyday conversation.

One of the first questions that a physician should ask is, "Does my state allow me to establish an ASC?" State policy may be a barrier. Nearly half of states currently allow cardiac procedures in the ASC setting. Half have a Certificate of Need, state law, or Department of Health guidelines in place to designate approvals, and a few states do not allow complex, invasive cardiac procedures in the ASC setting, regardless of CMS approval. For physicians in a state with these barriers, there are some steps that they can take. They can contact their local chapter of the American College of Cardiology and the local medical association. They can also engage the state-based Ambulatory Surgical Center Association and reach out to their representatives in the state legislature and governor's office.

## What advice do you have for a physician interested in transitioning to an OBL or ASC?

**Dr. Nair:** First, I would urge them to visit existing OBLs/ASCs, ask questions, and fully understand what you can do with a lab, also known as the art of the probable. That will provide firsthand the opportunity to see high-quality medicine being practiced with control over decision-making and staff retention and in a far better environment for themselves and their

patients. It will also help them determine the right model for their circumstances. Second, always seek out advice from a trusted expert. Having a partner that understands the requirements and how to navigate the potential challenges is indispensable.

Mr. Ferguson: Most physicians are risk adverse, and this is a big commitment. They must do their homework and determine if this is the right move for them from a personal, professional, and business standpoint. They must do the research and the calculations to determine if an OBL/ASC is a viable business decision in their area and which specialty or specialties are needed. They need to carefully select a partner. Aside from expertise, you need to evaluate a partner in terms of how much equity you are willing to give up, what level of service you will need in both the short and long term, and if the team is a good fit. Set realistic expectations of how long it takes to get up and running. An OBL buildout may take 6 to 8 months and an ASC buildout might take 18 months.

#### Parting thoughts?

**Dr. Nair:** I want to see doctors succeed at this because I believe it is an ideal solution for some of the health care problems we face in the United States, particularly escalating costs. I hear politicians all the time talk about how health care costs are unbearable, yet most of the decisions they make continue to raise rather than lessen costs. One of the ways we can absolutely save billions of dollars in health care costs while still improving quality and patient satisfaction is to move more into an outpatient-based care system. The time is now.

Philips OBL and ASC Solutions—SymphonySuite—offers expertise in the out-of-hospital industry for cardiovascular and endovascular labs in addition to a full range of services, partners (such as Horizon Solutions), and a comprehensive portfolio of products with unique reward programs\* to open an OBL, ASC, or hybrid lab for hospital-affiliated or independent physician ventures. To learn more about the Philips SymphonySuite solution visit www.philips.com/OBL.

<sup>1.</sup> Centers for Medicare & Medicaid Services. Medicare program: changes to hospital outpatient prospective payment and ambulatory surgical center payment systems and quality reporting programs; revisions of organ procurement organizations conditions of coverage, prior authorization process and requirements for certain covered outpatient department services; potential changes to the laboratory date of service policy; changes to grandfathered children's hospitals within-hospitals; notice of closure of two teaching hospitals and opportunity to apply for available slots. Accessed May 26, 2023. https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf

Bain & Company. Ambulatory surgery center growth accelerates: is medtech ready? Accessed May 30, 2023. https://www.bain.com/insights/ambulatory-surgery-center-growth-accelerates-is-medtech-ready

<sup>\*</sup>Not all customers will qualify. Subject to program agreement.