Case Study: Market Development and Innovation in Vietnam

Cerebration 2015
NUS Business School

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Introduction

As lifestyles in emerging countries improve due to higher disposable incomes, the prevalence of non-communicable diseases, particularly cardiovascular diseases, and the demand for superior healthcare services and products is increasing.

The country director of Vietnam faced a very challenging market and a barrage of questions in every quarterly business review. While Medtronic considers emerging markets the greatest source of growth, the Vietnamese market has grown at a tepid 10-12% in the last few years. It has become critical to understand why, in a country where 33% of all deaths were attributable to cardiovascular diseases, people were not getting the life-saving therapies that they need and Medtronic can provide.

Medtronic’s cardiovascular business accounts for 46% of its *global business and 58% of its business from emerging markets. Its portfolio covers a wide range of products for the treatment and management of coronary artery diseases, cardiac arrhythmias, and structural heart disorders requiring repair/replacement of heart valves. These products are usually used by interventional cardiologists for procedures conducted inside a catheterization lab (cath lab) or by surgeons in the operating theatre.

The cardiovascular challenges in Vietnam include a precarious regulatory regime, a fledgling public reimbursement system, low awareness within the population, limited access to facilities, and dearth of trained physicians. These challenges present a distinct need for innovation in order for Medtronic to provide life-saving therapies to the Vietnamese market. Harness your business acumen, your insights on healthcare and technology, and help us answer this question:

“How do we accelerate access to care for the many untreated cardiac patients in Vietnam?”

Corporate Overview

History

Earl Bakken and his brother-in-law, Palmer Hermundslie started Medtronic in 1949, operating out of Earl’s garage, as a repair shop for medical instruments. Bakken was a graduate student in electrical engineering at the time, at the
University of Minnesota. He eventually abandoned his studies to focus on Medtronic. Through his repair business, Bakken became acquainted with Dr. C. Walton Lillehei, who was to become a pioneering heart surgeon, then working at the University of Minnesota Medical School. Lillehei was frustrated with the pacemakers in those days since they were large, cumbersome and needed to be plugged into the wall socket, making them and consequently the patients vulnerable to power blackouts. On one fateful occasion, during Halloween of 1957, a power failure occurred and a pacemaker-dependent pediatric patient of Dr. Lillehei’s died. This prompted Lillehei to approach Bakken, urging him to solve the problem. Bakken went back and used a transistorized metronome to create the first external battery-powered pacemaker. After successful laboratory testing, Bakken left his prototype at the hospital to work on a more refined device for patients. However, when he returned to the hospital the next day, much to his surprise, his prototype was already in use for a patient. With this pioneering invention, Medtronic transitioned from a repair shop to a medical devices company and over the years brought many innovative developments to electrical devices, including expanding their applications to more complex, yet life-preserving tasks such as defibrillation and cardiac resynchronization therapy. By 1960, Medtronic had expanded its product line beyond pacemakers into monitoring instruments, gastrointestinal stimulators and other special instruments. However, a financial crisis and growing pains from increasing scale and heavy spending on R&D, Medtronic faced bankruptcy, prompting Medtronic to seek capital from a local VC firm, Community Investor Enterprises, who agreed to invest. This equity obligation proved a transformative turning point for Medtronic. Its new VC benefactor instituted strict financial controls and compelled Earl and Palmer to give his enterprise a mission.

**Mission Statement**

In 1960, Earl Bakken gave his company a formal mission statement, one that continues to this day and remains at the core of Medtronic’s strategic compass.

a. *To contribute to human welfare* by application of biomedical engineering in the research, design, manufacture, and sale of instruments or appliances that alleviate pain, restore health and extend life.

b. *To direct our growth in the areas of biomedical engineering* where we display strength and ability; to gather people and facilities that tend to augment these areas; to continuously build on these areas through education and knowledge assimilation; to avoid participation in areas where we cannot make unique and worthy contributions.
c. **To strive without reserve for the greatest possible reliability and quality** in our products; to be the unsurpassed standard of comparison and to be recognized as a company of dedication, honesty, integrity and service

d. **To make a fair profit on current operations** to meet our obligations, sustain our growth and reach our goals.

e. **To recognize the personal worth of employees** by providing an employment framework that allows personal satisfaction in work accomplished, security, advancement opportunity, and means to share in the company’s success.

f. **To maintain good citizenship as a company**

**Strategy**

Medtronic’s global growth strategy is driven by 3 ideas, considered universally applicable across cultures and business environments – improving clinical outcomes, expanding access and optimizing efficiency. Aimed at achieving these objectives, Medtronic has formulated the following strategy:

**Therapy Innovation:** This initiative is driven by Medtronic’s mission of alleviating pain, restoring health and extending life by providing better products and innovative therapies. Medtronic aims to identify unmet clinical needs, develop therapies to address those needs, and integrate those solutions into the medical ecosystem as a higher standard of care.

**Globalization:** Medtronic operates in more than 160 countries across the globe and recognizes that the next wave of growth will be driven by emerging markets. However, the strategies needed for success may require addressing market-specific needs. It is critical for the long-term success of Medtronic to provide solutions that can be tailored to fit the local healthcare environment.

**Economic Value:** Rising global healthcare costs pose a substantial concern from a societal standpoint as well as from an individual’s affordability. Therefore, Medtronic must innovate and transform solutions, offerings and business models to address these issues to deliver greater economic value and optimize the care delivery value-chain.
Medtronic’s Business

Medtronic broadly operates in 4 business groups which are further divided into smaller business units.

1. Cardiovascular Group (CVG)
2. Diabetes group
3. Restorative Therapies Group
4. Minimally Invasive Therapies Group (MITG): – formed from accumulating most of legacy Covidien offerings (as part of a $ 43 billion acquisition in 2015)

Cardiovascular Group (CVG)

The cardiovascular group consists of 4 business units:

Cardiac Rhythm & Heart Failure: CRHF is the oldest and largest business unit of Medtronic, with annual global sales of USD 5.25 billion. This business unit develops, manufactures and sells products for diagnosing, treating and managing cardiac rhythm disorders (arrhythmias) and heart failure. These products include implantable devices for managing arrhythmias and treating atrial fibrillation, leads and delivery systems and information / monitoring systems for the management of patients with cardiac arrhythmia and heart failure. The primary products marketed by this business are implantable permanent pacemakers (PPM), implantable cardioverter defibrillators (ICDs), implantable cardiac resynchronization therapies (CRT-P and CRT-D), catheter-based ablation systems for atrial fibrillation and patient arrhythmia diagnostics. These devices are generally implanted in a catheterization lab (Cath lab) by an electro physiologist (EP).

Coronary & Structural Heart (CSH): CSH accounted for ~ 3 billion USD globally, in 2015 and comprises the coronary and Structural Heart BUs. The coronary business develops devices for interventional treatments for coronary artery disease. These devices clear the path of the coronary arteries, otherwise clogged by plaque deposits, improving blood flow. Products offered by the coronary division include diagnostic catheters and wires for diagnostic angiograms and balloons, guiding catheters, guide wires, bare-metal-stents (BMS) and drug eluting stents (DES) for percutaneous coronary intervention (PCI) procedures and renal denervation. PCI procedures are performed in a cath lab, by an interventional cardiologist.
The Structural Heart BU offers therapies for treating heart valve disorders and other structural diseases, such as Coronary Artery Bypass Graft (CABG) surgeries. Products include heart valve repair, replacement valves, perfusion systems, positioning and stabilization systems for beating heart revascularization surgery and surgical ablation products. These procedures generally involve minimally invasive / invasive surgical procedures wherein the heart valves are delivered and implanted, either in a cath lab by an interventionist or in the OT by a cardio-thoracic surgeon.

**Aortic and Peripheral Vascular (APV):** The endovascular division accounting for ~ 1 billion USD in 2015, globally, provides products for the treatment or abdominal aortic aneurysms (AAA), dissections, transections and peripheral artery disease. Primary products for APV include stent grafts for treating AAA and thoracic aneurysms and peripheral vascular interventions. These procedures are generally performed in a cath lab by either an interventional radiologist with specialty training in endovascular implantations or by vascular surgeons.

More recently, Medtronic established the Hospital Solutions Group which aimed at transforming the company from being a product focused company to one that is solutions focused. The Group emerged in Europe responding to a market need to reduce cost of healthcare delivery. The Group began by partnering with hospitals to solve for operational efficiencies with a team of lean sigma consultants. The acquisition of NGC enabled Medtronic to offer a complete suite of Cath lab Managed Services including turnkey set up and installation, optimization, facilities management and growth programs. Medtronic delivers this by contracting with the hospital through a multi-year agreement. A description of the array of potential offerings for cath lab-managed services is given in exhibit 3. In the US, the Group focused on disease management and hospital efficiency management to increase value and reduce costs. To this end, Medtronic acquired the integrated healthcare provider, Cardiocom, to manage chronic patients outside the Hospital setting by combining Cardiocom’s telehealth services and Medtronic’s remote diagnostics and monitoring technologies embedded in some of its Cardiac devices, thereby improving patient outcomes and reducing hospital readmissions. Medtronic continues to lead that transformation by combining its own organic capabilities with inorganic market relevant acquisitions to meet the local market needs.

Hospitals in Southeast Asia face many of the same hurdles as hospitals in other markets but with its own emerging-market nuances. They are challenged with improving clinical workflows, managing supply chain and material costs, constrained capital budgets and delivering treatment to the patient at the lowest possible cost in the shortest time. Awareness of disease conditions, physician skills, referral pathways and infrastructure capacity are very poor. The
Hospital Solutions approach will play a significant role in combining Medtronic’s organic capabilities and inorganic assets to address the operational, technological and financial challenges that plague hospitals in Southeast Asia.

**Market Development Initiatives**

Innovation from Medtronic comes not only from its products, but also from its market development strategies. With longer product development cycles than other industries, these strategies are critical for Medtronic in growing the market size. These activities enable patients to access critical medical care.

**Dare to C.A.R.E.**: Dare to C.A.R.E. is a novel turnkey hospital vascular disease screening and risk management program. It is a validated program with 13 years of data from Anne Arundel hospital in Maryland. Developed by the Heart Health Foundation in 2000 to help drive more patients to seek care for vascular and heart disease, the program is now being offered to select heart and vascular institutes and hospitals through an exclusive partnership with Medtronic. DTC motivates patients to take action by educating and engaging them through outreach programs in order to overcome the diagnostic challenges for vascular disease. Please refer to the Exhibit 7 for further details about the logistics.

**Healthy Hearts For All (HHFA):** Healthy Hearts For All (HHFA) is a program that Medtronic launched in India in order to reduce patient “drop-out” of the care pathway by addressing barriers encountered at each stage. Cardiovascular disease is one of the most pressing problems in India and is responsible for 1/3 of Indian deaths. Problems revolving around accessibility, availability, and affordability prove to be barriers in each step of the patient care pathway. Through a combination of physician education, patient education, and patient financing, HHFA is able to provide high quality cardiac diagnostics and treatment for every member of society. Please refer to the Exhibit 5 for further details about the project.

**STEMI Program:** STEMI, which stands for ST Elevated Myocardial Infarction, is a heart attack caused when a blood clot completely blocks a coronary artery, blocking the supply of blood to the heart. These are emergency cases in which patients need to undergo angioplasties and therefore need access to the appropriate medical attention immediately. It is also the name of an initiative aimed at saving lives by improving outcomes and treatment costs for heart attack patients by optimizing the patient care delivery pathway (Exhibit 7). Medtronic, in partnership with global initiatives, physician and hospital partners has developed and executed regional projects to design and implement practical models for STEMI patient management and reperfusion. Within Jakarta, Indonesia, the STEMI
program resulted in roughly twice as many affected patients getting the primary (emergency) angioplasties that they needed. The program encompasses the following activities:

1. Sharing know-how and training the participating hospitals and KOLs on how to maximize the use of the referral network to treat STEMI patients
2. Collecting and interpreting information to identify inefficiencies and root-causes of prevailing problems.
3. Building and optimizing the referral networks for STEMI patients using a hub and spokes model (Exhibit 7);
4. Tracking the effectiveness of the program and implementing improvements

_Cath lab Interventional Therapies in the Hospital_

Main area of focus will be procedures performed in a catheterization lab. A catheterization lab (Cath lab) is an examination room inside a hospital, with diagnostic imaging equipment for visualizing cardiac arteries, chambers of the heart, aortic arteries and peripheral arteries to find and treat any blockages or abnormalities that are discovered. In a hospital, cath labs are generally owned by the cardiology practice in the hospitals because most of the procedures are angiograms and PCI. The main procedures performed inside the cath lab are elaborated below. A more intuitive understanding of the same can be gained by visiting [http://watchlearnlive.heart.org/](http://watchlearnlive.heart.org/).

**Coronary Angiograms (CAG):** An angiogram is a diagnostic procedure using x-ray images to discover blockages in coronary arteries so that the patient may seek further corrective treatments such as angioplasties (PCI) or coronary artery bypass surgeries (CABG). During an angiogram, a thin tube called a catheter is placed into a blood vessel in the groin (femoral artery) or just above the elbow (brachial artery). The catheter is guided to the area of interest. Then a special dye (contrast material) is injected into the vessel to make the area show clearly on the X-ray pictures. An angiogram can also be used for finding bulges in bloody vessels called aneurysms, which may then be further treated by vascular surgeons.

**Percutaneous Coronary Intervention (PCI):** also known as angioplasty is a non-surgical procedure that uses a catheter (a thin flexible tube) to open up a coronary artery, blocked by plaque buildup, by placing and inflating a balloon (sometimes covered with a metallic structure called a stent) to compress the plaque and open up the artery. PCI improves blood flow, thus decreasing heart-related chest pain (angina), making you feel better and increasing your ability to be active. A catheter is inserted into the blood vessels either in the groin or in the arm. Using a special type of X-ray, the catheter is threaded through the blood vessels into the heart where the coronary artery is narrowed.
When the tip is in place, a balloon tip covered with a stent is inflated, compressing the plaque and opening up the arterial channel for better blood flow. The gross prevalence in Vietnam, of coronary artery disease is \( \sim 29000 \) per million.

**Permanent Pacemakers (PPM) Implantation:** A permanent pacemaker is a device that uses electrical impulses to correct irregular, specifically slow, heart rates, called bradycardia. Modern pacemakers don’t just correct heart rates but also store and relay information on the status of the patient’s heart condition to his physician. Pacemakers are custom-programmed for each patient and implanted by an electro physiologist inside a cath lab. In Vietnam, the gross prevalence of bradycardia is 4800 per million.

**Implantable Cardioverter Defibrillator (ICD) Implantation:** is an implantable device which defibrillates the heart in the event of ventricular fibrillation (VF: quivering of the heart usually followed by flat lining – sudden cardiac death), fast ventricular tachycardia (FVT) and also serves the function of a pacemaker (for bradycardia). The device is therefore capable of correcting most life-threatening cardiac arrhythmias. The gross prevalence of sudden cardiac death in Vietnam is \( \sim 1500 \) per million.

**Cardiac Resynchronization Therapy (CRT) Implantation:** is a pacing device for desynchronized beating of the right and left ventricles, such as in heart failure (HF) patients. A CRT-D, in addition to treating ventricular de-synchronies and bradycardias, provides defibrillation therapies in the event of FVT and ventricular fibrillation (fast-paced quivering of the ventricles). The gross prevalence, in Vietnam, for all desynchrony/HF conditions is \( \sim 1500 \) per million.

**Aortic (EVAR/TEVAR):** Abdominal endovascular aneurysm repair (EVAR) is a minimally invasive alternative, which can be performed in a cath lab that results in reduced recovery times versus those in open surgery. An aortic abdominal aneurysm (AAA) is a localized bulging of the aortic artery, whose rupture can be fatal. In an EVAR procedure, a stent graft (covered stent) is implanted over the affected area using a catheter, providing an alternative path for blood flow, relieving the aneurysm of pressure. The gross prevalence of AAA in Vietnam is \( \sim 430 \) per million.

**Peripheral Angioplasty – Peripheral Artery Disease (PAD):** This is an angioplasty to treat peripheral artery disease. PAD is the blockage of blood vessels other than the heart and brain. The legs are a common sight for PAD. The interventional treatment is similar to a PCI in principle and involves the delivery of a balloon and stent (if required) over the affected area. The expanding balloon compresses the plaque, thereby increasing blood flow. Though the disease is not perceived as life threatening by patients as it may not present any serious symptoms, if left untreated,
the disease can lead to gangrene and amputation, which further increases the risk of death within the first year of treatment to 50%. The gross prevalence within Vietnam for the disease is ~ 5700 per million.

Vietnam

Country Overview

Vietnam continues to be one of the emerging “dragons” in Southeast Asia with a strong GDP growth of 5.8% in 2014. With the government focused on improving the nation’s healthcare, both, the pharmaceutical and the medical-device industries have strong growth potential.

Healthcare in Vietnam is plagued by the same problems that other developing countries have: accessibility, affordability, and quality. However, Vietnam is doing relatively better than its South East Asian counterparts. In a WHO study in 2010, Vietnam was ranked 131st in the world in terms of total healthcare expenditure per capita at 213 USD per capita; which is higher than Philippines, Indonesia, and Cambodia. It currently spends 6.4% of its GDP on healthcare, which is also higher than its regional peers. Positive policy reforms and bureaucratic consensus within the country puts an emphasis on prioritizing healthcare spending.

Key to these reforms has been the move toward equitable universal coverage of social health insurance in Vietnam. It has adopted UHC (approved 2012) as a national strategy with an aim to make health services affordable while maintaining quality. The goal is to expand coverage to at least 70% of the population by 2015, and 80% by 2020. Another goal is to reduce out-of-pocket payments to less than 40% of total health care spending by 2015. However, challenges remain as low enrollment rates persist, and out-of-pocket payments remain at around 60%. Even with the efforts from the government, healthcare coverage in Vietnam is still very much an issue. For interventional procedures, regardless of type of procedure, the maximum reimbursement available is only about USD 2000 per procedure, which cannot cover most types of cases aside from angiograms and simple PCIs. The patient himself must therefore pay the remainder of the bill.

Similar to most developing countries, the disparity between the different socio-economic classes in terms of ability to access and afford healthcare is evident. In a population of 91.6 million as for 2014, the inequality gap is significant. The social classes in Vietnam can be divided as per their income earnings, and classified as social classes A, B, C, D, and E. While the middle class is growing, it is mainly happening in the urban areas, and the class E
population age 15+ still comprises 39.4% of the Vietnamese population. Classes D and E usually cannot afford the out-of-pocket payments they require to seek even the most necessary treatments. Vietnamese people often self-medicate for mild illnesses, such as slight fevers, sore throats, stomach aches or headaches, especially in children. They think that these illnesses are not serious and can be treated with common medicines. Moreover, most people do not like the hassle of going to healthcare establishments as it is generally time consuming.

**Healthcare Landscape**

**Public:**

The public healthcare system is available to patients with and without social health insurance. Public hospitals are largely funded by taxes and marginally by insurance premiums. However, hospital services are of low quality, the waiting times are long and crucial medical equipment is lacking. The improvements in infrastructure and staffing in public hospitals have not matched the growth in the number of insured patients. In addition, the system is ineffective and bureaucratic and the paperwork is complicated. As a result, access to virtually all public hospitals is an issue. Statistically, three to four patients share one hospital bed; therefore, only people on low incomes use the social insurance system. Better-off patients often ignore their social insurance and choose on-demand sections at public hospitals. These sections allegedly offer higher quality and less waiting, partly because the paperwork is less complicated. However, the fee is higher. As more people opt for on-demand sections in public hospitals, they too have become overcrowded. In addition, most patients from the countryside travel to the cities for treatment believing that city hospitals have more experienced doctors.

**Private:**

The ineffectiveness of public hospitals has given rise to private healthcare. The number of private hospitals has risen from 40 in 2004 to 170 in 2014. Doctors also open private clinics. Compared to public hospitals, private hospitals and clinics are more technologically advanced and offer better customer service. Nevertheless, because the costs are significantly higher, the majority of the population cannot afford private healthcare. Moreover, small private hospitals may not have doctors with long experience, unlike public hospitals. Therefore, for serious illnesses, people still prefer public hospitals. In order to overcome this problem, the Ministry of Health has drafted plans to support the private segment financially in order to attract more patients. A large number of physicians working in public hospitals would, in the afternoon, work in private practice. They siphon patients who can pay, to the private clinic or
hospital. While this practice improves remuneration to doctors and also offloads some of the patient burden from the public hospitals, it reduces the availability of physicians in public hospitals, which remain the centers of care delivery for the bulk of the general population. Therefore, an alternative plan under consideration is to transfer some patients from public hospitals to private ones without increasing their medical costs. Private healthcare spending represented 56.9% of total health expenditure in 2013, although this percentage has steadily declined since 2005. The proportion represented by public healthcare has increased significantly, from 26.4% to 43.1% in the same period. This is due to the relaxation of rules on social insurance eligibility and the economic slowdown, which has made private healthcare unaffordable to many.

**Interventional Practice in Vietnam:**

Interventional cardiology practice in Vietnam started quite recently, in 1997 at the Bach Mai hospital in Hanoi and witnessed rapid growth thereafter with centers sprouting up in Ho Chi Minh and Hue city.

There are about 45 cath labs across Vietnam (~15 in North Vietnam, 7 in Central and 3 in South Vietnam) and the country is currently adding 4 to 5 cath labs every year. In terms of number of procedures, cath labs in Vietnam on average are quite burdened, delivering more than 1000 procedures annually per cath lab, as is evident from Exhibit 3. However, it should be noted that caseloads in North Vietnam tend to be much higher than in South and Central Vietnam, leading to an imbalanced use of cath labs across Vietnam.

There are currently about 70 PCI implanters (ICs), 40 cardiac rhythm implanters (mostly EPs), 26 aortic implanters (mostly IRs) and 20 peripheral implanters (mostly IRs) across the country. However, generally, physicians may work at 2 to 3 hospitals to augment their incomes.

In Vietnamese cath labs, most of the procedures performed are diagnostic angiograms (72%) and PCIs (24%), with only about 3% accounting for heart rhythm (CRHF) implants, aortic implants and peripheral implants.

As the market develops and patient volumes increase, Vietnam would need to add further capacity at a faster pace.

**Patient Journey**

Insured patients register for care at a primary facility (Commune Health Stations) where health insurance funds are then allocated to pay for their care. The referral process is formally outlined in the health insurance scheme. If
patients bypass their primary facility without a referral letter they will pay higher co-payments. In some cases, the Commune Health Stations need to refer patients directly to tertiary hospitals, bypassing district and provincial hospitals due to lack of facilities or capacity. Since such cases are considered bypassing, health insurance reimbursement is only 30%. In many areas, since primary facilities cannot yet serve insured patients, provincial hospitals get crowded with a large number of primary care patients. While uninsured patients are not subject to such gate-keeping measures for rational use of health services, they must pay more for higher-level facilities. In this context, there is generally, a lack of patient trust in the professional capacity of lower levels, which is increasing the demand for medical care at higher levels, even for treating mild cases.

At any facility, regardless of insurance status, every patient can be referred to higher-level care. While the public sector does not generally refer patients to the private sector, the private providers often refer to the public sector. Providers operate independently and medical records do not follow the patient, resulting in poor continuity of care and weak linkages between facilities, particularly, when it comes to downward referral of patients.

In the emergency route, a patient will only approach a hospital’s emergency facility when he feels a pain in his chest, a sensation, which he associates with his mortality. Once in the emergency room, he will be assigned to either a general cardiologist under internal medicine or an interventional cardiologist (IC), a matter over which, the patient has little knowledge or choice. If referred to a general cardiologist, the cardiologist would diagnose him and either prescribes drugs or refers him further to an interventional cardiologist (CAG + PCI), an electro-physiologist (PPM/ICD/CRT) or an interventional radiologist / vascular surgeon (Aortic / peripheral).

However, navigating through this pathway is tortuous because the present systems and infrastructure rely on - How the patient perceives his physical symptoms, his decision to seek a diagnosis and his journey inside the hospital, where he once again relies on the expertise and decisions of his doctor. Furthermore, there is significant overcrowding in public hospitals, which combined with bureaucracy and underpaid medical personnel compels patients to bribe officials and physicians in order to proceed further with treatment.

General cardiologists can be a significant bottleneck in the pathway as they are not motivated to refer their patients to an IC, believing that their patients are unlikely to return to them for care once they are treated by an IC. Therefore, many patients are stuck within the system, and either remain undiagnosed or on prescription medication, sometimes till an emergency emerges.
Medical Devices

Vietnam medical device regulations are under the jurisdiction of the Department of Medical Equipment and Health Works (DMEHW) within the Ministry of Health (MOH). In addition, locally manufactured medical devices are regulated by the Ministry of Science and Technology (MOST). In the past, foreign medical device companies were only allowed to sell their devices through local wholesale distributor firms. These local firms would then distribute to smaller distributors in their network. However, this restriction was removed at the end of 2008, and some foreign medical device companies have now set up their own distribution in Vietnam. The registration process for medical devices in Vietnam is different for medical devices which are imported and those which are manufactured locally. Devices which are imported are not required to be registered. Instead, a product specific import license will suffice. To obtain a product specific import license, foreign medical device companies are required to submit a quality declaration letter, proof of regulatory approval the original product catalog, the instructions manual containing technical specifications (with their Vietnamese translation), as well as a Certificate of Free Sale from the device’s country of origin. Furthermore, building relationships with key opinion leaders (KOLs) and regulatory authorities is important to navigate through the system. However, since most hospitals in Vietnam are government-owned, procurement is done through formal tendering.

Competitive Landscape

The competitive scenario within the interventional cardiology universe varies substantially among types of procedures and consequently the product suppliers for each.

Coronary: procedures account for the largest market, also evidenced from the bulk of procedures in the cath lab attributable to angiograms and PCIs. As a result, the coronary space is very populated, with 22 players, all international, vying aggressively to win market share. In recent times, many Indian manufacturers have entered the market with low prices causing significant price erosion. However, the top player, Biosensors takes 15% of the share, followed by Medtronic, BCS and Abbott, each taking 11%, together claiming ~ 50% of the pie. Since medical devices in Vietnam are largely unregulated, building relationships across the public healthcare system is not only critical to success, but also poses substantial compliance risks, with the backdrop rampant corruption in the country. The activities of other competitors have been primarily focused on capturing market share with low prices and lobbying with physicians and offering sponsorships for conferences etc.
CRHF: The pacemaking business, being more technology-intensive and requiring specialized support such as case-specific programming, is concentrated, with the top 2 (Biotronik – 50% and Medtronic-CRHF – 45%) out of the 4 active participants capturing 95% of the market with Sorin and SJ claiming the remaining 5%. Competitive activity in this field is concentrated on market development efforts through physician training and patient financing since case-volumes are substantially lower than for other procedures.

APV: The market for aortic and peripheral vascular therapies is still in its infancy as evidenced by the fact that there were only 124 aortic cases and only ~ 142 peripheral arterial interventions, conducted in Vietnam in FY15, and these too were confined to a few hospitals, with Bach Mai (Hanoi) and Cho Ray (Ho Chi Minh city) accounting for 35% and 22% of all aortic procedures respectively. Within aortic procedures (EVAR/TEVAR), Medtronic enjoys an 82% market share with Bolton taking 15% and Ella taking the remaining 3%. As the market grows, competition is expected to intensify, as competitors, especially Bolton lobby more aggressively with physicians and government agencies and offer private incentives.

Within peripheral vascular therapies, Medtronic carries a market share of 33%. The market size, however, remains small. One barrier in growing peripheral vascular therapies has been the perception that PAD is not immediately life-threatening.

**Problem Statement**

You are tasked with critically examining and assessing the patient treatment pathways for cardiovascular diseases, focusing on cardiac interventions in Vietnam.

Based on this assessment, and your understanding of the technology landscape, socio-economic and regulatory challenges and capacity constraints, we expect the team to identify treatment opportunities for Medtronic in Vietnam, propose innovative business models, and prepare an implementable plan. The key differentiators in assessing the responses from the teams would be the extent of innovation that they bring into their plans, the impact that can be measured, and the ease of piloting and scalability.
APPENDIX

Exhibit 1: *Global Sales (all figures in Billion USD)

By Business

- CVG, 9.36
- RTG, 6.75
- MITG, 2.387
- Diabetes, 1.762

By Region

- US, 11.3
- Non-US Developed, 6.37
- Emerging Markets, 2.58

*excluding USD 8.2 billion from Covidien after reconciliation
Exhibit 2: Current Case-load in Vietnamese Cath labs

<table>
<thead>
<tr>
<th>S No.</th>
<th>Name of Procedure</th>
<th>No. of procedures (Annual)</th>
<th>No. of procedures per cath lab</th>
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<tr>
<td>1</td>
<td>CAG (Angiograms)</td>
<td>33000</td>
<td>733</td>
</tr>
<tr>
<td>2</td>
<td>PCI (angioplasties)</td>
<td>11000</td>
<td>244</td>
</tr>
<tr>
<td>3</td>
<td>Pacemaker</td>
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<td>4</td>
<td>ICD</td>
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<td>1</td>
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<td>CRT (P &amp; D)</td>
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<td>1</td>
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<td>Aortic (EVAR/TEVAR)</td>
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<td>3</td>
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</tr>
</tbody>
</table>

Exhibit 3: Hospital Solutions – Cath lab Managed Services
Exhibit 4: Overview of Vietnamese Healthcare system
Exhibit 5: HHFA

HHFA attempts to reduce patient drop out of Care pathway by addressing barriers at each stage

- Patient visits General Physician
- Patient referred to Cardiologist in the hospital
- Adoption of therapy by the patient

HHFA team
- Therapy sales Rep
- BMI Associate
- Patient Counselor, Finance Counselor

How HHFA addresses barriers
- Therapy awareness amongst physicians
- Diagnostic tools at physician clinics
- Conduct screening camps
- Improve referral physician
- Tie-up with implanters and hospital management
- Conduct patient outreach campaigns
- Conduct implanter education along with businesses
- Counsel patients to alleviate fears and answer questions
- Offer loans on devices
- Offer low or bar services for poor patients

Messaging and tools

- Physicians
  - Physician education material—brochures
  - Education: TEPP, CME
  - Communication on EV added with increase in diagnostic & implant revenue

- Providers
  - HHFA pitch to hospitals for partnerships
  - PR/Marketing of financing program
  - Communication on EV added with increase in diagnostic & implant revenue

- Patients
  - Patient education material—leaflets, standees, posters
  - Patient counseling kiosk inside partner hospitals
  - Finance offering for the product

- BU heads, core sales team
  - Quarterly updates on EV to leadership team
  - Communication to employees on EV through Leadership town hall and Medtronic Newsletter
  - Joint customer feedback
Exhibit 6: Dare to C.A.R.E

SCREENING LOGISTICS

- Patient Enters Program
  - PCP Referral to Dare to CARE*
  - Events & Outreach
  - Participant Referral

- Patient makes appointment for DTC

- Patient Screened

- Results explained & sent to PCP

- No disease
  - Patient eligible for screening in five years

- Disease detected
  - PCP and patient decide on best treatment option

WOM Marketing

VALUE OF THE DTC APPROACH

- Dare to C.A.R.E. is a continuous approach to managing heart and vascular health in local communities.
  - Continuous operation: DTC is not single-event based
  - Continuous following and tracking: Program helps ensure proper care and follow-up, with less patient fall out
  - Demonstrates value through action; measurable metrics (diagnosis/procedures) vs. soft metrics (exposure/awareness)
  - Financially sustainable; increased ROI with program tenure
Exhibit 7: STEMI