**Cureitall Hospital**

**Background**

Cureitall Hospital started as a small clinic in the outskirts of Appletree City north of Atlanta, Ga. The founder Dr. Philip Goode turned Cureitall into a success story almost overnight. He performed a series of very uneventful triple bypass surgeries which put Cureitall on the map immediately.

Ever since Dr. Goode has stepped more into a managerial position watching his clinic grown into a 1600 staff 3 building goliath of a hospital with some of the best cardiologists in the nation. People come from all over the world to have the heart’s checked and procedures done. Hotels have established around it to accommodate patients’ friends and family. Appletree City can thank its commercial growth to the success of Curitall Hospital.

In the year 2013 the stent manufacturer, the distributor, the cardiology staff and the Cureitall Hospital, Inc. were sued on grounds of malpractice in a class action suit from several former patients and relatives of deceased patients for the use of a type of stent that was reported in the Journal of Cardiology issue of April 2004. It was then taken off the market, however mistakenly used in at least 50 procedures since 2004. How was it that the staff and administrative team did not realize that they had defective stents in stock for so long is still something they cannot comprehend?

Dr. Felix Goode, son of Dr. Philip Good and now CEO of Cureitall Hospital, Inc. has heard of your LSS consulting firm and would like to hear what you have to say about it.

1. From what you learned in the LSS GB program, how would you first approach this case?
2. You have been granted access to the cardiology department’s historical data. How can you turn this information into valuable decision making information? (See attached spreadsheet- Exhibit 1)

There are two types of stents:

1. A very high quality stent type A that can be in a patient’s heart for the next 10 years. But it costs twice as much as,
2. Type B stent has to be changed every 5 years it is a very good quality but not as long lasting as Type A.

Type B stent started deteriorating in some cases right after the 3 year mark and the complications were immediately noticeable some people had to be readmitted to the hospital, others died. Ultimately a family member noticed a pattern and contacted other patients and family members to start a lawsuit process. (See attached spreadsheet – Exhibit 2)

**What Are the Risks of Having a Stent?**

Risks Related to Angioplasty

Angioplasty, the procedure used to place stents, is a common medical procedure. Angioplasty carries a small risk of serious complications, such as:

•Bleeding from the site where the catheter was inserted into the skin

•Damage to the blood vessel from the catheter

•Arrhythmias (irregular heartbeats)

•Damage to the kidneys caused by the dye used during the procedure

•An allergic reaction to the dye used during the procedure

•Infection

Another problem that can occur after angioplasty is too much tissue growth within the treated portion of the artery. This can cause the artery to become narrow or blocked again. When this happens, it's called restenosis (RE-sten-no-sis).

Using drug-eluting stents can help prevent this problem. These stents are coated with medicine to stop excess tissue growth.

Treating the tissue around the stent with radiation also can prevent tissue growth. For this procedure, the doctor threads a wire through a catheter to the stent. The wire releases radiation and stops cells around the stent from growing and blocking the artery.

Restenosis of a Stent-Widened Coronary Artery

Figure A shows the coronary arteries located on the surface of the heart. Figure B shows a stent-widened artery with normal blood flow. The inset image shows a cross-section of the stent-widened artery. In figure C, tissue grows through and around the stent over time. This causes a partial blockage of the artery and abnormal blood flow. The inset image shows a cross-section of the tissue growth around the stent.

Risks Related to Stents

About 1–2 percent of people who have stented arteries develop a blood clot at the stent site. Blood clots can cause a heart attack, stroke, or other serious problems. The risk of blood clots is greatest during the first few months after the stent is placed in the artery.



Your doctor will likely recommend that you take aspirin and another anticlotting medicine, such as clopidogrel, for at least 1 month or up to a year or more after having a stent procedure. These medicines help prevent blood clots.

The length of time you need to take anticlotting medicines depends on the type of stent you have. Your doctor may recommend lifelong treatment with aspirin.

Stents coated with medicine may raise your risk of dangerous blood clots. (These stents often are used to keep clogged heart arteries open.) However, research hasn't proven that these stents increase the chances of having a heart attack or dying, if used as recommended.

Risks Related to Aortic Stents in the Abdomen

Although rare, a few serious problems can occur when surgery or a fabric stent is used to repair an aneurysm in the abdominal aorta. These problems include:

•A burst artery (aneurysm rupture).

•Blocked blood flow to the stomach or lower body.

•Paralysis in the legs due to interruption of blood flow to the spinal cord. This problem is very rare.

Another possible problem is the fabric stent moving further down the aorta. This sometimes happens years after the stent is first placed. The stent movement may require a doctor to place another fabric stent in the area of the aneurysm.

**What Are the Most Common Causes of Stent Failure?**

Causes of stent failure can include poor placement, the use of bare metal stents, and mechanical fatigue. Success rates can vary by device and medical professional; people with substantial experience in stenting procedures, for example, can experience more positive patient outcomes. In some cases, stent failure happens from the start, when the device cannot be placed properly and another measure needs to be considered to address a narrowed artery.

Stents are used to address stenosis, a medical complication where the walls of an artery thicken and narrow, limiting blood supply. It is a particular concern around the heart, where interruptions in blood supply could cause a heart attack. In an angioplasty procedure, a medical professional can remove built up plaque on the wall of the artery before inserting a stent to hold it open. Stents fail if soft tissue grows over them, narrowing the artery again, or when they buckle, break, or collapse.

One potential cause of stent failure is iatrogenic, meaning that it is the doctor’s fault. Some damage to the walls of the artery can occur during placement, which increases the chance of soft tissue growth over the stent. Doctors with more experience working in advanced facilities can be more successful, as can those using devices they know well. Problems with stent design can be a factor as well; some products are hard to insert, for example, which increases the risk of tissue damage.

Another issue is the construction of the stent. Historically, these devices were made from bare metal, which created an excellent matrix for soft tissue to grow on. Many devices now are designed to slowly secrete drugs over time to block clotting and cell growth. Drug eluting stents, as they are known, tend to experience a higher success rate. If there are concerns about stent failure, this type of device may be recommended.

Mechanical fatigue can be a factor in stent failure. Metals used in medical devices are subjected to extensive testing, but microscopic analysis of failed stents can show signs of cracks, pitting, bending, and fractures. These indicate that some metals may not be suitable for long-term use, as they could break down over time. Strain might cause the stent to fail, putting the patient at risk of a serious medical complication if the issue cannot be identified in time. When a failure is linked to obvious metal fatigue, it can be reported to a medical database, allowing regulators to monitor the ongoing safety of specific devices on the market and ultimately determining if they should remain available for sale.