

As seen in Hospital News

Advances in Modern Technology

By Ross Swanson and Cathy DiNardo

Continual change is clearly evident in today's healthcare environment. Over the last decade, advances in practice standards, along with new technology and devices, has been more prominent than ever, especially within the cardiovascular specialty.

But, while clinical advances are no doubt intended to improve patient care, they simultaneously cause hardship for some programs when considering increased costs or reimbursement shortfalls. Drug eluting stents are perhaps the best example of what Corazon refers to as a "disruptive technology"—an advance that upsets the status quo, though oftentimes, despite the initial transition, best positions a program for future clinical and fiscal success.

The Past:

Until a few years ago, coronary angioplasty procedures were performed using bare metal stents (BMS), tiny metal devices that act as a scaffold to keep the coronary artery open and prevent blood flow blockage. Patients realized moderately successful results, but restenosis (re-clogging) rates could be as high as 30% within the first three months following a procedure.

The medical device industry strived to develop a better way to keep arteries open, so a new stent was introduced that contained "embedded" medication that could be delivered over a prescribed amount of time to a very discrete location in the coronary artery. These new models, called "drug eluting stents" (DES), were designed to diminish the inflammatory response that typically occurs in the blood vessel wall after a stent is deployed. This response was also believed to actually trigger the high restenosis rates seen with the traditional bare metal stent.

These devices were subjected to multiple, in-depth clinical trials and were approved by the FDA in April 2003. By the fall of that year, widespread clinical adoption had already begun in the United States.

In the first clinical trials, drug eluting stents showed acute restenosis rates of 0%, and this was clearly an extraordinary outcome compared to previous stent technology. In clinical practice, patient outcomes were also much better than the BMS; and, though physicians were unable to duplicate the 0% restenosis rates, rates as low as 10-15% were not uncommon and still remarkable. They were an industry revolution.

But, acceptance of this new technology was not without its challenges. There are serious clinical and financial implications of using these devices because programs must adapt their practice standards to the meet the changing technology while remaining clinically responsible to patients and fiscally responsible to the hospital bottom line.

Clinically, there were initial questions about the safety and effectiveness of using these stents in all patients. The results and initial clinical outcomes at hospitals that had already adopted this technology were extremely favorable, and

interventional cardiologists throughout the U.S. continued to request this emerging standard for angioplasty procedures.

Unfortunately, the financial issues have been much more difficult to resolve. The costs for the new drug-coated stents are approximately \$3,000, which far exceeds the \$1,000 cost of bare metal devices. Furthermore, reimbursement rates are not covering the costs of the procedures, even with new DRGs for angioplasty with a DES.

The Present:

Though the financial situation with drug eluting stent use is at present beginning to improve, certain strategies are necessary to maintain optimum profitability. Corazon recommends several strategies for keeping costs down, while not sacrificing the clinical benefits of using these DES.

Strategy #1 – Negotiation: In 2003, the Cordis/Johnson & Johnson CYPHER DES was the first approved in the U.S. This monopoly on the market, though short-lived, allowed the company to set the price of the CYPHER stent. One year later, Boston Scientific's TAXUS stent received approval, and now Guidant may enter the DES product line. This increasingly competitive market has driven the stent prices down slightly over the past two years, though the cost of the stent procedure (including the stent, other cath lab supplies, and personnel) are not in line with the reimbursement rates.

One way to combat this imbalance is to negotiate your supply costs with multiple vendors. Corazon recommends approaching several companies for a bid and bargain for the best price. This may be difficult as many hospitals already have preferred relationships with one vendor. Hospital purchasing agents can also secure lower prices with larger volume orders though inventory management must be a controlled process as these devices have a relatively short shelf-life.

Strategy #2 – Benchmarking: Since these devices are costly, it is absolutely necessary to track DES utilization per case. In Corazon's experience, programs using an average of 1.8 – 2.2 stents per case are not making optimal use of these expensive items. Corazon recommends achieving a benchmark of about 1.2 – 1.4 stents per case.

Utilization rates should be tracked by each cardiologist to ensure consistent utilization for all cases. Looking at outcomes in conjunction with each practitioner's use rates can indicate over- or under-utilization, which could be costing your organization money in lost stents [i.e., unaccounted for] or ineffective use of the supply (the patient may have been better treated using non-invasive means), or on the other hand, re-do procedures or subsequent surgeries.

Strategy #3 – Inventory Management:

Since they are coated with medication, drug eluting stents have a much shorter shelf-life than their bare metal predecessors. These limited expiration dates can cause problems with inventory management. Loose inventory

processes that were geared to the longer shelf lives of bare metal stents may not meet the needs of the tight inventory protocols needed for these drug-coated models.

Corazon often recommends that larger, high-volume programs hire a dedicated inventory clerk to manage these costly supplies. Smaller programs with lower volume can instead establish a computerized system for inventory management. Corazon also recommends that facilities with little DES experience work with a supply chain vendor to manage the purchasing process.

The Future:

Clinically, there have been improvements made to the devices over the past two-and-a-half years, including a wider variety of sizes made available and facilitated ordering processes. For instance, since DES inventory cannot sit on hospital shelves for long periods, the companies have implemented fast-track ordering and shipping processes. The response rates for product turnaround on DES orders have a faster lead time than many others in the industry. Though this is usually atypical of medical device companies, it is yet another example of adaptation in the face of advances in technology.

Another associated advance in technology relates to stent placement during and post-procedure. Older stents have a tendency to move slightly, so many programs are now using intra-coronary imaging techniques such as intravascular ultrasound (IVUS) to monitor the stent and ensure it has not migrated within the artery.

Looking ahead, it seems that DES use rates will continue to increase across the country in all cardiovascular programs. At Corazon we anticipate that this technology, already considered the 'standard of practice' for angioplasty will become even more integral to the Cath Lab as time passes. But, as hospitals gain experience adapting to changes, such technology will be considered far less 'disruptive' and the adoption will be more streamlined.

It is likely that the near ideal clinical outcomes associated with DES will become even better over time, as operators and techniques improve, and bottom lines will not feel as strong an effect ...until the next new advance comes along!

Ross Swanson is a Senior Consultant and Cathy DiNardo is a Consultant with Corazon, a national leader in specialized consulting services for cardiovascular program development from strategic business planning through clinical implementation. Corazon combines business planning, market and financial analysis, feasibility studies, clinical operations, Heart Hospital design, best practice benchmarking, and staff education for newly established or existing cardiovascular programs.

Corazon is a 2003 Ernst & Young Entrepreneur of the Year Company. Call 412-364-8200 or visit www.corazon-consulting.com.