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## Storm Warning: Big Changes Approaching in PCI

By James Burns

The future of cardiovascular care is going to be a bumpy ride. Where the last five years have seen dramatic improvements in care delivery, the next five to ten years will likely surpass these achievements. Drug eluting stents, and primary and unsupported angioplasty are just a few of the topics that are now or will soon be relevant issues in cardiac care.

From its humble beginnings in 1977 as standard balloon angioplasty, Percutaneous Coronary Intervention (PCI) procedures now include techniques such as coronary artery stents, angiojet, and rotablator. Of all of the PCI procedures, coronary artery stenting now accounts for 80% of all performed. Stenting, the process of inserting and scaffolding a mesh like tube in an artery to prevent the formation of future blockages, continues to grow at an astonishing rate. This process is fast becoming the gold standard in coronary care.

There are two primary reasons for this anticipated phenomenal interventional growth: the much-anticipated introduction of drug eluting stents (DES) and the engagement of the practice of primary angioplasty.

These DES are coated with medicine that helps prohibit intimal hyperplasia, which is the process of excessive cell growth over the stented area. It is the leading cause of reocclusion and stent failure. Preliminary results from 12-month studies showed that less than 1/2 % of cases had reocclusion. These results have experts predicting a wide spread acceptance of these stents in their first years of availability. It is estimated that 80% of all stents used will be drug eluting by the third year of availability.

While these DES study results are very promising for the future of cardiac care, they also present new challenges to facilities that perform these services. Primarily, the high cost of the DES coupled with the anticipated widespread utilization and limited reimbursement in the first years on the market will create a huge economic hardship on many programs because the stents are estimated to cost anywhere from \$2,800 to \$4,800 per unit.

With the current average stent usage of 1.4-1.5 devices per case, the cost of the stents alone could use up 75% of the reimbursement. While DES are expected to receive FDA approval in the late spring of 2003, CMS is not anticipated to develop any type of reimbursement strategy until 2004, with private and commercial payors one year after that. In terms of bottom-line impact, a program could be losing upwards of \$2000 per case on each PCI patient treated with DES. The impact this could have on even the strongest of programs is clear.

As full service programs are looking toward methods to distinguish themselves in the marketplace while offering their community the most innovative care available, the practice of Primary Angioplasty, the protocol of getting acute cardiac patients to the cath lab as quickly as possible, is being embraced. This necessitates the full cath lab services being available 24 hours a day, seven days a week. Lytic therapies are bypassed in favor of more rapid treatment. Many recent studies have shown that getting a patient treated in a cath lab, rather than initiating drug therapies, is the optimal approach in treatment of acute events. Mortality rates were consistently higher for patients first treated with thrombolytic therapies than for those that had initial treatments in the cath lab.

While Primary Angioplasty has been proven as clinically superior to other options for the AMI patient, it presents some logistical and financial problems for facilities. Being able to offer cath lab services to patients at any time can be a scheduling nightmare. In addition to trying to juggle on-call and general cath lab staffing for these programs, facilities need to attract and retain the Cardiologist manpower to lead them. With an estimated 1000 Cardiologist positions expected to remain unfilled in the next five years, this could prove to be a difficult task.

Coupled with the staffing needs of a Primary Angioplasty program are the financial resources needed for operation. High salaries for skilled staff, on-call premiums, recruitment, and the general costs to keep a cath lab running uninterrupted, impinge upon the bottom line. Moreover, CMS and other payors currently do not offer any additional payments for services offered in off-hour emergent settings.

Another PCI development is the capability of facilities to perform interventional services without the onsite support of an open heart surgery (OHS) program, referred to as Unsupported Angioplasty. Once thought to be unsafe, this practice is gaining acceptance in some markets. While the risks of angioplasty have continued to diminish, many, including the American College of Cardiology (ACC), are reluctant to endorse this practice. A recent clinical trial in the Mid-Atlantic region of the United States (Atlantic Cardiovascular Patient Outcomes Research Team, or Atlantic C-PORT) showed promising results as a limited number of centers without OHS programs were permitted to perform emergent interventions. Still, a great deal of debate over the need and risks of unsupported angioplasty remains. In fact, many states still have regulations prohibiting it. Most experts concur that major changes or general acceptance of this acute PCI strategy are yet years away.

What options do these changes present to existing or developing CV programs? In the case of unsupported angioplasty, programs that are considering this route should carefully weigh all of the options available. Although risks for PCI have significantly decreased in recent years, these procedures are still very complicated. Any adverse event in a program without OHS support available onsite could be detrimental to that facility's program. Very rural, isolated centers may be more appropriate candidates for this practice, provided that a viable transport arrangement with a full service center is in place. An organization considering unsupported angioplasty should ask: Is the risk and exposure worth it compared to the investment in developing the full service line that will allow the capture of the higher OHS revenues?

Established programs concerned about competitors initiating unsupported angioplasty programs, can rest easy for at least the next few years. Many Cardiologists are reluctant to perform these procedures on high-risk patients, and the ACC is unlikely to change its stance on the issue any time soon. Consequently, volumes at these unsupported PCI centers will be low. Furthermore, although the growth rate in OHS is not as high as that in PCI, OHS still provides some of the highest margins in CV care. Thus, patients that would be pulled away from full service centers will not necessarily draw huge amounts of revenue with them.

There are several complex issues surrounding DES and Primary PCI for facilities that offer OHS and interventions. The majority of hospitals' missions seek to provide the most up-to-date and beneficial health care available. There is a very grey area when that care involves creating huge cost deficits. Steps can be taken, however.

First, when developing a game plan to deal with these changes, engage in an open and continuing dialog with Cardiologists, for they are the "quarterbacks" of the CV team. Understand what they want in terms of new technology and practice changes and make them aware of what impact these care decisions can make on the overall program. Elicit their input on cost saving measures that could counteract the losses created by these changes; examine patient selection and appropriateness protocols; and discuss vendor flexibility for inventory cost savings.

Another important tactic is to similarly engage managers and staff in the discussion of how these changes could negatively impact the facility. Often times some of the best suggestions for improving efficiency and decreasing waste comes from front-line clinicians who deal daily with such problems.

Thirdly, focus on the importance of inventory management. High cost DES should not sit and expire on hospital shelves. Again, encourage vendor flexibility, since better-priced products can help defray some of the high expense created by practice changes.

Fourthly, enter into discussions and negotiations with vendors, especially those who offer high-priced new technologies. Look at options to decrease price in return for other purchases. Explore bundling and consignment options and don't be afraid to ask for more favorable terms. The worst that could happen is that you will be told "no."

Lastly, and perhaps most importantly, get all players on board with appropriate documentation and coding. CMS tracks data to make future changes in reimbursement based on billing codes, even though those codes may not currently change payment. Furthermore, many groups that rate quality and outcome measures use coding data to risk stratify. Inappropriate coding could make the program look much worse than it actually is.

In summary, the road ahead is going to be turbulent to say the least. No one can really predict what the future holds. In summary, DES may, in the long term, not be the panacea they are predicted to be and go the way of Rezulin and Seldane. Or, they could be more advantageous than ever imagined for treating acute coronary artery disease. Either way, program administrators have little to lose in taking the time to evaluate their program and plan their future. At the very least, they can gain some insight into operations and costs, while at the most, they can make their program more ready to weather the storm approaching in PCI.



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