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FEATURE STORY

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could your financial health be heading for heart break?

Costly drug-eluting stents could dramatically alter projected demands for cardiac surgical services.

There's no denying how important cardiac services are to many organizations' bottom lines. But a recent clinical advance with the potential to dramatically alter treatment patterns threatens to significantly reduce the ability of cardiac programs to offset operating losses in other service lines or cover organizational overhead expenses.

AT A GLANCE

- **A new type of stent may alter demand and affect the financial performance of cardiovascular programs.**
- **Patients electing angioplasty instead of CABG as the preferred initial treatment for coronary stenosis may increase.**
- **The need for CABG procedures to correct restenosis following angioplasty may decline.**

Stents: The Heart of the Matter

At issue is a new device used to treat patients with coronary stenosis, a potentially life-threatening narrowing of the arteries that occurs as fatty substances (plaque) build along the arterial walls. There are two basic approaches for dealing with this condition. One approach is to perform a coronary artery bypass graft (CABG), a surgical procedure in which a cardiovascular surgeon takes a portion of a healthy blood vessel from another part of the body and grafts it to the affected artery or arteries to reroute blood flow around the area of blockage. The other approach is to perform a percutaneous transluminal coronary angioplasty (PTCA), a nonsurgical procedure in which a cardiologist threads a catheter to the area of blockage and then inflates a balloon attached to the catheter to widen the artery by pushing plaque against the artery wall. About 80 percent of the time, one or more wire mesh tubes (stents) are inserted into the artery to help keep it open after a PTCA.

Although stents have improved the long-term success of angioplasties, 15 to 30 percent of PTCA patients experience a recurrence of arterial blockage,

restenosis, and require either an additional angioplasty or a CABG procedure within six months. Because restenosis is so common, many surgeons opt for the CABG procedure outright.

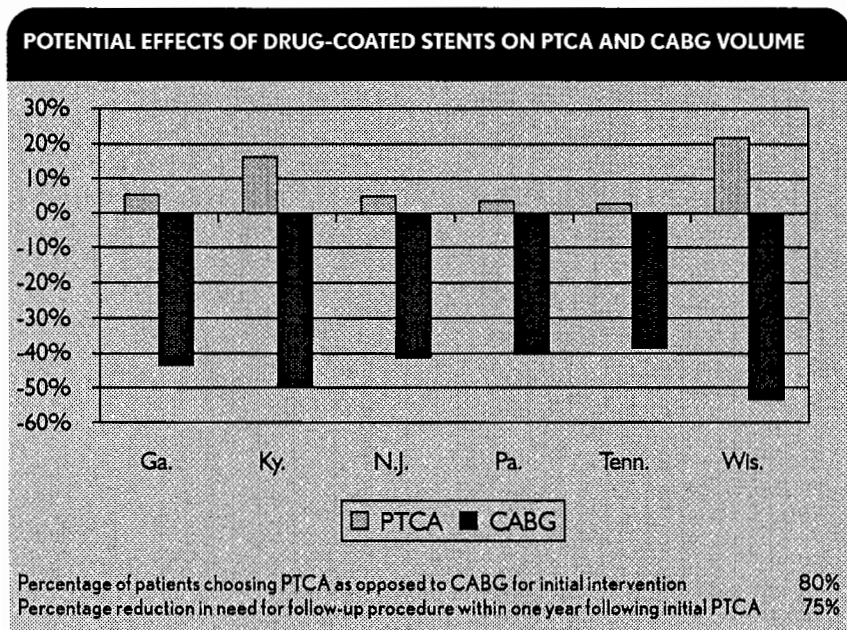
Recently, researchers have been examining the use of stents covered with drugs to prevent or minimize the likelihood of restenosis—and they're seeing dramatic short-term success in clinical trials.

While this success has clinical circles abuzz, the potential implications to financial managers could be equally stunning. This clinical breakthrough is occurring at a time when many hospitals and health systems are expanding the scope of their cardiovascular programs and making large capital investments in cardiovascular facilities and equipment. Numerous organizations are weighing investments in state-of-the-art facilities built solely to offer the full spectrum of cardiology and cardiac surgery services in a single location.

Healthcare organizations making major capital investments in new or expanded cardiac surgical services may face serious financial risk if drug-eluting stents nearly eliminate restenosis in treated arteries. Two factors will come into play: First, the percentage of patients undergoing angioplasty who require follow-up CABG surgery would decline sharply. Second, many more patients likely would initially opt for angioplasty, instead of undergoing the more invasive CABG procedure, particularly if drug-eluting stents are shown to have long-term clinical efficacy for high-risk patient populations.

The Financial Forecast

The financial impact of drug-eluting stents on cardio-



Widespread use of drug-eluting stents may not accelerate historical rates of growth in angioplasty demand in all markets. The potential impact on angioplasty volume is less than 10 percent in three of the six markets studied in a scenario using moderate assumptions: 70 percent of patients elect angioplasty as their initial procedure; drug-eluting stents are used in only 40 percent of angioplasties; and follow-up procedures to treat restenosis drop by 40 percent. The significant decline in repeat angioplasties tends to offset the higher percentage of patients initially choosing angioplasty.

vascular programs depends on the projected change in the volume and mix of angioplasties and CABG surgeries, as well as the effect on the cost structure and payment for these services.

Some observers have forecast that the demand for CABG procedures, which account for 70 to 80 percent of all open-heart surgery, will decline by 50 percent as a result of drug-eluting stents. Others have taken a more cautious stance, pointing out that drug-eluting stents may only delay, not significantly reduce, the rate of restenosis. This issue will not be resolved until long-term outcomes data are available.

However, should drug-eluting stents be found to reduce restenosis of treated arteries over the long term, many of the demand equations for interventional cardiology and open-heart surgery will be significantly altered. An analysis of current and projected future use in six metropolitan markets confirms that CABG volumes would drop about 40 to 50 percent (not accounting for modest growth due to population growth and aging) in a "maximum-effect" scenario—in which 80 percent of patients elect angioplasty as their initial procedure; drug-eluting stents are used in 80 percent of angioplasty procedures; and the need to surgically treat restenosis following use of a drug-eluting stent drops by 75 percent compared with procedures using traditional stents.

Adding to this financial strain is major concern regarding the high cost of drug-eluting stents. The devices cost about \$3,200—about three times the cost

of traditional stents. Although CMS began to provide incremental payment for drug-eluting stents in April 2003, the payment falls far short of the projected cost of the devices. Thus, the financial performance of affected cardiology services will worsen, at least in the short run.

The combination of high cost and low payment for drug-eluting stents, however, may discourage their use. Cost is considered a major reason for the low market penetration of drug-eluting stents in Europe, estimated at 10 percent in the first eight months after their approval in April 2002.

Another possibility is that long-term reductions in rates of restenosis will not approach the short-term results. The potential impact on CABG volume is much smaller (less than 10 percent in three of the six markets studied) in another scenario using more moderate assumptions: only 70 percent of patients elect angioplasty as their initial procedure; drug-eluting stents are used in only 40 percent of angioplasties; and the need to surgically treat restenosis following use of a drug-eluting stent drops by only 40 percent compared with procedures using traditional stents.

A surprising corollary outcome in both scenarios is that four of the six markets would experience only small changes in angioplasty volume (plus or minus 5 percent), with the significant decline in repeat angioplasties tending to offset the higher percentage of patients initially choosing angioplasty. This finding suggests widespread use of drug-eluting stents will not accelerate historical rates of growth in angioplasty demand in all markets.

Heading for a Heart Break?

Pro forma analyses for programs of various sizes suggest that drug-eluting stents could reduce the combined contribution margin of interventional cardiology and open-heart surgery services by 30 percent or more.

A large, regional cardiovascular program planning a \$30 million capital investment to accommodate projected demand for 1,500 open-heart surgeries (including 1,200 bypass procedures) and 3,900 angioplasties in 2005, had forecast a combined contribution margin of \$32 million (38 percent) for interventional cardiology and open-heart surgery services at those volume levels. A revised pro forma was developed

CLINICAL STUDIES OF DRUG-ELUTING STENTS

The clinical efficacy of drug-eluting stents is demonstrated clearly in initial outcomes data from two large clinical trials reported at the Transcatheter Cardiovascular Therapeutics conference in Washington, D.C., in September 2002.

At six months, a TAXUS trial reported in-stent restenosis rates of 2.3 percent and 4.7 percent for two versions of a stent coated with the drug paclitaxel, compared with a rate of 20.6 percent for combined control groups using bare stents, according to presenter Antonio Colombo, MD.

At nine months, the SIRIUS trial reported an in-stent restenosis rate of 3.2 percent for a stent coated with the drug sirolimus, compared with a rate of 35.4 percent in the control group. The SIRIUS trial also produced favorable results for high-risk populations, including patients with diabetes, multivessel disease, prior angioplasty, and prior infarctions, according to lead investigator Jeff Moses, MD.

based on 1,000 open-heart surgeries and 4,100 angioplasties, volumes consistent with the assumptions used in a "maximum-effect" scenario for drug-eluting stents (i.e., a 40 percent decline in CABG surgery and a 75 percent decline in follow-up surgeries to treat restenosis following angioplasty).

Other key assumptions for the revised pro forma were that drug-eluting stents would be used for 80 percent of the angioplasties, and that the added payment for the drug-eluting stents would cover only half of their added cost. The revised financial projections indicated a combined contribution margin for interventional cardiology and open-heart surgery services of only \$22.6 million, a drop of \$9.4 million (29 percent). To understand potential effects for healthcare providers, a detailed comparison of revenue and expense projections before and after accounting for the effect of drug-eluting stents is useful. Some significant findings follow.

Effect on open-heart surgical services. Net patient revenue from open-heart surgery declines \$10.4 million because of a 33 percent drop in surgical case volume (40 percent fewer CABG procedures, with no change in cardiac-valve procedures). At the same time, direct operating expenses associated with open-heart surgery services decline \$7.8 million because of the lower case volume (variable expenses include salary and benefits for staff in the surgical suite, the cardiovascular intensive care unit, and the telemetry unit, as well as the cost of supplies and ancillary services). The net effect of these events would be a \$2.6 million decline in the contribution margin for open-

heart surgical services.

Effect on coronary angioplasty services. Net patient revenue from coronary angioplasties increases \$6.5 million, reflecting a 4 percent increase in volume and a 13 percent increase in per-case payment. Payment rates for patients with drug-eluting stents are assumed to be \$1,800 higher than payment rates for patients with traditional stents. Meanwhile, direct operating expenses associated with coronary angioplasty and diagnostic catheterization services increase \$13.3 million, with virtually all of the increase (\$13.1 million) attributed to the higher cost of drug-eluting stents (assuming cardiologists will use 1.7 drug-eluting stents per patient at \$3,200 per stent, compared with 1.5 traditional stents per patient at \$1,200 per stent). The net effect of these events is a \$6.8 million decline in the contribution margin for coronary angioplasty patients.

Overall effect. Overall, net patient revenue for open-heart surgery, coronary angioplasty, and diagnostic cardiac catheterization services declines \$3.9 million. The higher volume of angioplasties and higher payment rates for patients with drug-eluting stents are unable to compensate for the loss in revenue resulting from the 33 percent decline in surgical volume. At the same time, total operating expenses increase \$5.5 million. The higher cost associated with drug-eluting stents overwhelms the significant reduction in variable costs within the cardiac surgery program.

What to Do

The long-term effects of drug-eluting stents on interventional cardiology and cardiovascular surgery services may not be known for two or three years. The likely short-term effects will include less demand for surgical treatment of restenosis following angioplasty, and lower revenue and higher costs for hospitals providing coronary angioplasty and open-heart surgery services.

Healthcare organizations considering major new investments in cardiac surgery or angioplasty services should carefully monitor the results of clinical trials that address the long-term effects of drug-eluting stents, and then adjust demand models accordingly. Organizations should also aggressively pursue higher payment for drug-eluting stents based on their long-term clinical and financial benefits by lobbying government agencies and negotiating managed care contracts that adequately pay for the added cost. Plans to initiate or expand open-heart surgery services should also be scrutinized to confirm market and

WHAT'S IT MEAN?

Percutaneous transluminal coronary angioplasty (PTCA):

An invasive procedure performed in a cardiac catheterization laboratory to widen a narrowed coronary artery and improve blood flow to the heart.

Stent: A wire mesh tube used to prop open an artery that's recently been cleared by a catheter-based treatment, such as PTCA.

Stenosis: A stricture or narrowing of an artery.

Restenosis: Recurrence of arterial narrowing following a CABG procedure or coronary angioplasty.

Coronary artery bypass graft (CABG): A surgical procedure that involves taking a portion of a healthy blood vessel from another part of the body and grafting it to a blocked coronary artery to reroute blood flow around the blockage.

FEATURE STORY

The scenario depicted shows net patient revenue from open-heart surgery declining \$10.4 million as a result of a 33 percent decrease in patient volume following adoption of drug-eluting stents.

IMPACT OF DRUG-ELUTING STENTS ON CARDIOVASCULAR REVENUE AND EXPENSES

	Before Drug-Eluting Stents	After Drug-Eluting Stents	Impact of Drug-Eluting Stents	Percentage Impact of Drug-Eluting Stents
Open-Heart Surgery				
Number of procedures (CABG + valve)	1,495	1,004	(491)	-33%
Net patient revenue	\$33,994,000	\$23,603,000	(\$10,391,000)	-31%
Operating Expenses				
Salary/benefits—operating room	\$2,764,000	\$1,856,000	(\$908,000)	33%
Salary/benefits—CVICU/telemetry unit*	\$5,303,000	\$3,546,000	(\$1,757,000)	-33%
Supplies	\$10,382,000	\$7,540,000	(\$2,842,000)	-27%
Ancillary services	\$6,057,000	\$4,068,000	(\$1,989,000)	-33%
Other direct expenses	\$1,275,000	\$1,014,000	(\$261,000)	
Total	\$25,781,000	\$18,024,000	(\$7,757,000)	-30%
Contribution margin	\$8,213,000	\$5,579,000	(\$2,634,000)	-32%
PTCAs/Dx Caths†				
Number of PTCAs	3,907	4,082	175	4%
Net patient revenue				
PTCAs	\$37,017,000	\$43,555,000	\$6,538,000	18%
Dx Caths (w/o open-heart surgery or PTCA)	\$13,210,000	\$13,210,000	\$0	0%
Total	\$50,227,000	\$56,765,000	\$6,538,000	13%
Operating Expenses				
Salary/benefits—cath lab	\$2,052,000	\$2,094,000	\$42,000	2%
Salary/benefits—telemetry unit	\$2,838,000	\$2,911,000	\$73,000	3%
Supplies	\$17,331,000	\$30,407,000	\$13,076,000	75%
Ancillary services	\$3,223,000	\$3,337,000	\$114,000	4%
Other direct expenses	\$974,000	\$974,000	\$0	
Total	\$26,418,000	\$39,723,000	\$13,305,000	50%
Contribution margin	\$10,599,000	\$3,832,000	(\$6,767,000)	-64%
Open-heart surgery and interventional cardiology				
Net patient revenue	\$84,221,000	\$80,368,000	(\$3,853,000)	-5%
Total operating expenses	\$52,199,000	\$57,747,000	\$5,548,000	11%
Contribution margin	\$32,022,000	\$22,621,000	(\$9,401,000)	-29%
	38.0%	28.1%		

*CVICU = cardiovascular intensive-care unit

†PTCA = percutaneous transluminal coronary angioplasty; Dx Caths = diagnostic catheterizations

DID YOU KNOW?

About 70 to 90 percent of coronary angioplasties involve the use of a stent.

Source: American Heart Association

financial feasibility using alternative sets of demand projections. In addition, cardiology and cardiovascular surgery should be treated as a single product line when developing clinical program strategies and facility plans, making it easier to reallocate resources in response to shifting patterns of demand.

Healthcare executives should be vigilant in the next three years as the delivery of cardiovascular services responds to the potential widespread adoption of drug-eluting stents. This emerging technology could have

profound effects on the financial performance of existing, expanding, or new cardiovascular programs. ■

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