

Will Drug-Eluting Stents Reduce Demand For CABG Procedures by 50 Percent?

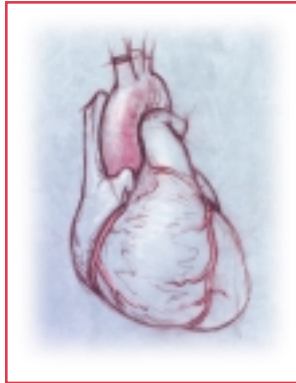
A series of recent articles in the medical literature, newspapers, and other publications have focused on the potential of drug-eluting stents to revolutionize the delivery of interventional cardiology services. Dramatic short-term reductions in restenosis rates following percutaneous transluminal coronary angioplasty (PTCA) have been achieved in clinical trials of the new technology. These reductions have led some observers to predict that the market for cardiac stents will double by 2005.

Potential Impact on Cardiac Services

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 health care organizations have created or are planning a heart center or cardiovascular institute. Often, a new, state-of-the-art facility is built to house such a venture, allowing the full spectrum of cardiology and cardiac surgery services to be offered in a single location.

Hospitals or health systems making major capital investments in new or expanded cardiac surgery services may face serious financial risk, however, if drug-eluting stents nearly eliminate restenosis of treated arteries. Two factors will come into play. First, the percentage of PTCA patients who require follow-up coronary artery bypass graft (CABG) surgery will decline sharply. Second, it is likely that many more patients will initially opt for angioplasty instead of more invasive cardiac bypass surgery, especially if drug-eluting stents are shown to have long-term clinical efficacy for high-risk patient populations.

In fact, some observers have forecast that the demand for CABG procedures, which account for approximately 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 and the need for revascularization. This issue will not be resolved until long-term outcomes data are available.



Strategies & Solutions for Managing the Effects of Drug-Eluting Stents

- Carefully monitor results of clinical trials that address the long-term effects of drug-eluting stents
- Adjust demand models for coronary angioplasty and open-heart surgery to reflect the long-term effects of drug-eluting stents, other anticipated technological developments, and the aging of the adult population
- 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 reimburse for the added cost of the service
- Reconsider strategies to initiate or expand open-heart surgery services, especially if revised demand projections suggest an inability to meet the Leapfrog Group standard of at least 500 CABG procedures per year
- Treat cardiology and cardiovascular surgery as a single product line when developing clinical program and facility plans, making it easier to reallocate resources in response to shifting patterns of demand

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The Potential Effects of High Cost and Low Reimbursement

A key concern is the high cost of drug-eluting stents, estimated at \$3,200 per device, or about three times the cost of bare-metal stents. Although CMS will provide incremental reimbursement for drug-eluting stents beginning in April 2003, the expected payment will fall far short of the projected cost of the devices. Thus, the financial performance of interventional cardiology services will also be negatively affected, at least in the short run, adding to the financial woes of some hospitals and health systems.

It is also possible that the combination of high cost and low reimbursement for drug-eluting stents will 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 following their approval in April 2002).

Outcomes from Recent Clinical Trials

Initial outcomes data from two large clinical trials reported at the September 2002 Transcatheter Cardiovascular Therapeutics (TCT) conference in Washington, D.C., clearly demonstrate the clinical efficacy of

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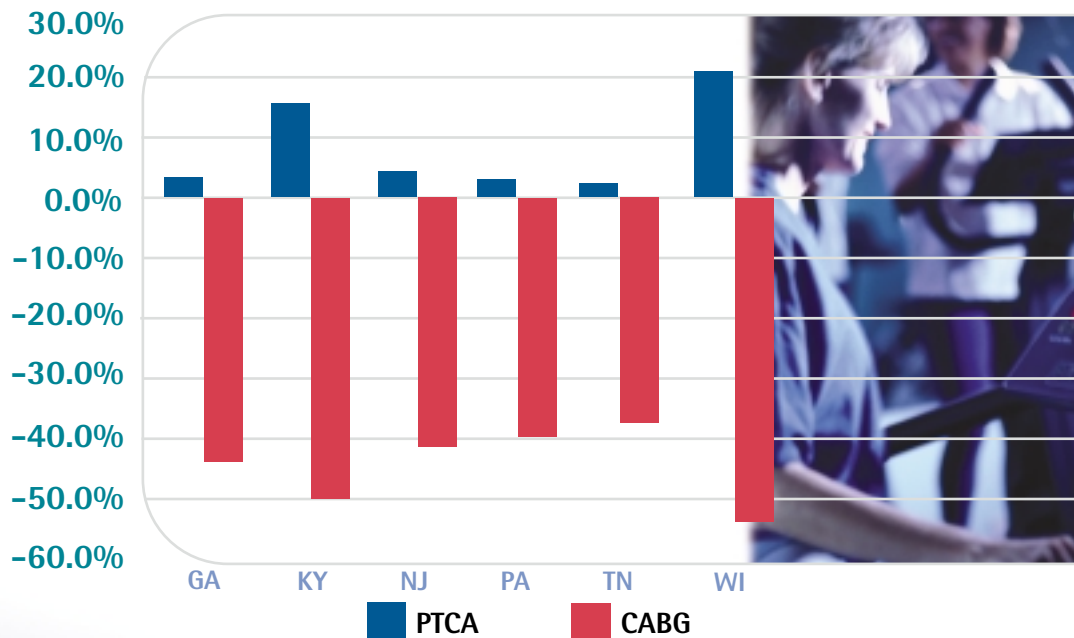
drug-eluting stents. At six months, the TAXUS research trial reported in-stent restenosis rates of 2.3 percent and 4.7 percent for two versions of a paclitaxel-eluting stent, compared to a rate of 20.6 percent for combined control groups using bare-metal stents.

At nine months, the SIRIUS trial reported an in-stent restenosis rate of 3.2 percent for a sirolimus-coated stent, compared to 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, multi-vessel disease, prior angioplasty, and prior infarctions.

in 80 percent of angioplasties, revascularization rates drop by 75 percent, and 80 percent of patients elect PTCA as their initial procedure.

However, the projected impact on CABG volume was much smaller in another scenario, in which we assume that coated stents are used in only 40 percent of angioplasties, revascularization rates drop by 40 percent, and only 70 percent of patients elect PTCA as their initial procedure. In this case, CABG volumes would drop by less than 15 percent in four of the six markets we examined and less than 30 percent in the others.

Potential Effect of Drug-Eluting Stents on PTCA and CABG Volume In Select Metropolitan Markets in Six States



Percentage of Patients Choosing PTCA as opposed to CABG for Initial Intervention80%
 Percent Reduction in Need for Revascularization within One Year Following Initial PTCA75%

Planning for the Future of Cardiac Services

Health Strategies & Solutions has estimated the potential effects of drug-eluting stents on PTCA and CABG volumes by modifying 2001 angioplasty and open-heart surgery use rates in six metropolitan areas, with adult populations ranging in size from 275,000 to 925,000. Our analysis confirms that CABG volumes would drop approximately 40 to 50 percent (not accounting for future population growth and aging) in all markets in a "maximum effect" scenario, in which we assume that coated stents are used

At the same time, there were very small changes in PTCA volume (plus or minus five percent or less) in four of the six markets in both scenarios, with the significant decline in repeat angioplasties tending to offset the higher percentage of patients initially choosing PTCA. This analysis suggests that widespread use of drug-eluting stents may not cause angioplasty use rates to grow any faster than recently observed growth rates of eight to 10 percent per year in many markets.

The financial impact of drug-eluting stents on cardiovascular programs

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depends on the potential change in the volume and mix of angioplasties and CABG surgeries, as well as the effect on the cost structure and reimbursement for cardiovascular services. 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 and 3,900 PTCA's 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.

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A revised pro forma, based on a 40 percent decline in CABG surgery, a 75 percent decline in revascularization rates following PTCA, and added reimbursement covering only half the added cost of drug-eluting stents, indicated a contribution margin of only \$22.6 million based on 1,000 open-heart surgeries and 4,100 PTCA's. Interestingly, the below cost reimbursement for drug-eluting stents accounted for 72 percent of the decline in contribution margin in this case, with only 28 percent attributable to the projected drop in cardiac surgery volume.

RUSS COILE JOINS HSS STAFF AS SENIOR STRATEGIST

Russ Coile, a nationally recognized health care futurist, has joined Health Strategies & Solutions as its senior strategist. Coile has



provided market forecasts and strategic advice to hundreds of hospitals, health systems, medical groups, health plans, and suppliers.

He conducts about 75 presentations annually to a wide national audience, including the American Hospital Association, the American College of Healthcare Executives, and the American College of Physician Executives. Coile is also a prolific writer, authoring 10 books and numerous articles. He publishes his own monthly newsletter, *Russ Coile's Health Trends*.

Most recently, Coile and Alan Zuckerman have coauthored a book entitled *Competing on Excellence*, which will be published by Health Administration Press this summer. Coile will be available to consult with HSS clients and conduct seminars and board retreats on emerging health care trends.

KEITH T. PRYOR TO SERVE AS HSS GOVERNANCE EXPERT

Keith Pryor, a noted expert on non-profit governance and management, has joined the staff of Health Strategies &



Solutions as its senior governance advisor. Pryor has over 20 years of experience in health care leadership and consulting, including positions as chief executive officer of the \$350 million Berkshire Health Systems, associate director of the Sloan Program in Health Administration at Cornell University, and managing director of Diversified Health Search.

He has authored numerous articles and conducted over 100 presentations during the last several years on board evaluation, education, and development. Pryor has also led national trustee discussion groups for the American

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Off the Press **Recent Articles**



"Competing in Today's Cloudy Environment," by Alan Zuckerman, November/December issue of *Spectrum*

"Healthcare Competitive Strategy: What Executives Need to Know in the 21st Century," by Alan Zuckerman, January issue of *COR Healthcare Market Strategist*

"Clinical Research Trials: Competitive and Financial Advantages," by Jennifer Jones and Alan Zuckerman, January issue of *Managing the Margin*

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On the Dais **Upcoming Presentations**



Amerinet

Craig Holm and Erica Baittinger: "Competitive Strategy in Health Care," January 23 in Warrendale, Pennsylvania

Christie Markham and Erica Baittinger: "Building a Competitive Women's Health Program," January 24 in Warrendale, Pennsylvania

American College of Healthcare Executives

Alan Zuckerman: "Strategic Planning: From Formulation to Action," January 13-14 in Key West, April 5-6 in Boston (in conjunction with VHA), April 10-11 in Hilton Head, and April 29-30 in New Orleans

Alan Zuckerman: "Advanced Competitive Strategy: How to Win the War for Markets and Share," February 20 tele-conference from Dallas, cosponsored by VHA and ACHE

North Carolina Chapter of the Healthcare Financial Management Association

Alan Zuckerman: "Revenue Enhancement Strategies for Hospitals and Systems: Moving Beyond Cost Cutting," February 28 in Pinehurst, North Carolina

KEITH PRYOR continued

Hospital Association on the subjects of community accountability and downsizing.

Pryor will be available to consult with HSS clients and conduct presentations on a variety of governance and organizational issues.

SHRADDHA PATEL TO SERVE AS HSS ANALYST

Shraddha Patel has joined Health Strategies & Solutions as an analyst. A recent graduate of Pennsylvania State University with undergraduate degrees in health policy and administration and science, Patel will assist HSS clients with a variety of data analysis and research projects.

Prior to joining Health Strategies & Solutions, Patel served as an administrative intern with the Chestnut Hill Pediatric Group in Philadelphia and as an extern for the Surgical Center of York in York, Pennsylvania.



Above | to r: Craig Holm, Alan Zuckerman, and Hugo Finarelli

For more information on drug-eluting stents, please contact one of our directors:

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