THE COST EFFECTIVENESS OF DRUG-ELUTING STENTS

An interview with Earl P. Steinberg, M.D., M.P.P.

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Prior to that, Dr. Steinberg spent 12 years as a full-time faculty member at Johns Hopkins University, where he was Professor of Medicine, Professor of Health Policy and Management, and the Founder and Director of the Johns Hopkins Program for Medical Technology and Practice Assessment. Dr. Steinberg currently serves on the Blue Cross Blue Shield Association's National Medical Advisory Panel and the Advisory Committee for the Harvard Medical School's Department of Health Policy.

An Advanced Studies in Medicine Senior Clinical Editor interviewed Dr. Steinberg regarding the cost effectiveness of drug-eluting stents, as well as the anticipated effect these devices will have on the treatment of patients with coronary artery disease.

ASIM: In general, how does one make a case for cost effectiveness to a hospital that has to pay for an expensive device without directly receiving the economic benefits of lower long-term healthcare expenditure?

Dr. Steinberg: Hospitals typically assess the cost effectiveness of any technology from their own perspective, as opposed to that of the patient, an insurer, or society as a whole. The way a hospital would view the cost effectiveness of an expensive new device, such as a drug-eluting stent, thus would depend on how the hospital is paid for the services it provides, and how the payment it receives compares to the incremental costs it incurs as a result of using the new type of stent.

When a drug-eluting stent is used instead of a bare-metal stent, there is not likely to be any difference in the cost of the hospitalization; that is, length of stay likely would not change. The difference would be the cost of the stent itself. The key issue, therefore, becomes the difference between the payment a hospital receives when it inserts a drug-eluting stent compared with a bare-metal stent.

Hospitals tend to be paid for a hospitalization on either a diagnosis-related group (DRG) basis (i.e., they receive a fixed amount of payment for a particular type of hospitalization) or on a discounted fee-for-service basis. Therefore, the cost impact on the hospital associated with the use of drug-eluting stents will depend on the amount by which the DRG payment, or the fee it receives on a discounted fee-for-service basis, increases when a drug-eluting stent is used instead of a bare-metal stent. If the increase in the payment the hospital receives is large enough to cover the incremental cost of use of the drug-eluting stent, the hospital will have an economic incentive to use the new stent. If the increase in payment is not large enough to cover the incremental cost, the hospital's primary economic incentive for using the new type of stent would derive from potential malpractice costs the hospital would incur as a result of not using the new type of stent. Other considerations would include the impact of the hospital's decision on its ability to retain or attract cardiologists and other physicians, as well as the impacts on patient volume.

Since drug-eluting stents are expected to reduce restenosis and, hence, repeated angioplasties or coro-
nary artery bypass grafting (CABG) procedures, the hospital, as well as the cardiologists and cardiac surgeons who perform angioplasties, are likely to see their revenue reduced as a result of the fewer repeated procedures. Thus, if the hospital does not receive an increase in its payment for the initial procedure that at least covers the incremental cost of the drug-eluting stent, both its short-term and long-term revenues will decrease.

If hospitals, at least initially, are going to lose money as a result of using drug-eluting stents, I expect hospitals to have 1 of the 2 following responses:

1. They will decide to use drug-eluting stents because it is the right thing to do vis-à-vis the patient, or because the cost consequences of not using them (e.g., malpractice and loss of high-revenue-producing physicians) are even greater than the incremental cost of using the new stents; or
2. They will promote greater use of CABG rather than percutaneous transluminal coronary angioplasty (PTCA) plus stenting.

**ASiM:** Will the new Centers for Medicare and Medicaid Services (CMS) reimbursement schedule enable hospitals to break even if they convert to universal use of coated stents?

**Dr. Steinberg:** That will depend on the amount by which CMS changes the DRG payment for the relevant DRG. CMS will be under tremendous political pressure to cover the incremental cost of drug-eluting stents. I suspect that CMS will try to anticipate what the price of these stents will be once more than 1 manufacturer has a drug-eluting stent on the market, and then increase the DRG payment accordingly. Even if CMS covers the full incremental cost of drug-eluting stents, hospitals and cardiologists will lose revenue as a result of the decrease in repeated procedures to treat in-stent restenosis.

**ASiM:** The introduction of stents in 1994 was initially associated with “sticker shock.” Their use was initially restricted to patients with poor angioplasty results. Many operators gradually increased the percentage of angioplasty patients receiving stents, such that the devices have become routine in the vast majority of interventions. Is this the paradigm for coated stents?

**Dr. Steinberg:** Hospitals can follow 1 of 3 strategies: (1) they can use the new stents on all patients; (2) they may not use the new stents on any patients; or (3) they can use the new stents on the subset of patients who are at highest risk for restenosis, for example, patients with a small-diameter coronary artery. Whether hospitals follow strategy 1 or strategy 3 will depend on whether future data show that the 6-month risk of restenosis is truly zero and whether the reduced rate of restenosis is sustained over time.

Given currently available data, I think it will be very difficult for hospitals to not use drug-eluting stents exclusively. I also believe insurers will pay the incremental cost of these stents, because they will recoup some or all of the incremental cost as a result of decreased repeated procedures for restenosis. If payments for these stents are not adequate, I would not be surprised to see the volume of PTCA plus stent decrease and the volume of CABG increase.

**ASiM:** How would you compare the economics of restricting the use of coated stents to high-risk subsets of patients and using intravascular radiation to treat restenosis in patients receiving bare-metal stents?

**Dr. Steinberg:** I am not familiar with the current costs associated with use of intravascular radiation to treat restenosis. However, the analysis that needs to be performed to answer your question is straightforward. Specifically, the answer depends on:

1. The incremental incidence of restenosis in low-risk patients who receive bare-metal stents compared with drug-eluting stents times the cost of treating restenosis, whether by intravascular radiation or cutting balloons, or new stents that can be placed within a stent, or other new treatments for restenosis; versus
2. The incremental cost of using drug-eluting stents in low-risk patients.

**ASiM:** Do you think the availability of coated stents will change the paradigm of revascularization in the United States? Specifically, will it divert patients away from surgery and toward angioplasty?

**Dr. Steinberg:** The availability of stents that markedly reduce the risk of restenosis will likely increase the proportion of revascularization procedures that are performed using PTCA rather than CABG. However, because there has already been a major shift toward PTCA plus stenting over the past decade, the increase may not be as great as one might think. In addition, as I mentioned above, the shift could actually go the
other way if payment rates for drug-eluting stents are not increased adequately.

**ASiM:** How may coated stents affect the nationwide annual volume of percutaneous interventions during the next decade?

**Dr Steinberg:** The availability of coated stents could increase the number of patients who undergo any type of revascularization because there is now a lower-risk alternative to medical therapy, as well as increase the proportion of patients who undergo revascularization via PTCA. I think the threshold for performing PTCA in the United States is already pretty low, though.

**ASiM:** Is it logical to think that a strategy of restricting coated stents to predefined high-risk groups is practical in the United States?

**Dr Steinberg:** I don't think so, unless future data are less compelling than currently available data. Given the publicity surrounding these new stents, and the increased availability of information via the Internet, I think Americans undergoing PTCA will demand that a coated stent be used, regardless of whether the patient is at high or low risk for restenosis. The threat of a malpractice suit in the event that a low-risk patient who received a bare-metal stent develops restenosis will be too high to ignore.

**ASiM:** Clinicians often base their practices on the “mother principle”—“I do for my patients what I would do for my mother.” Would your mother get a coated stent regardless of risk of restenosis?

**Dr Steinberg:** Definitely, given currently available data.

**ASiM:** How good are we at predicting restenosis in patients receiving bare-metal stents?

**Dr Steinberg:** Not as good as we could be. We know that the risk of restenosis increases as lumen diameter decreases and as lesion length increases. However, I suspect that statistical analyses could produce more accurate predictive models. On the other hand, such models would have to be exceedingly accurate to overcome the pressure to use coated stents. In addition, it may be more difficult to generate pertinent data once the Food and Drug Administration approves more coated stents.

**ASiM:** Is there evidence that coated stents are the great restenosis equalizer for all types of anatomy?

**Dr Steinberg:** This question is better answered by a cardiologist.

**ASiM:** If a short course of an oral drug, such as a rapamycin derivative, was effective, would it cost less when used in conjunction with a bare-metal stent compared with the cost of a drug-eluting stent?

**Dr Steinberg:** If by “cost” you mean total cost over some period of time, the answer to this question will depend on the price of the oral drug and the length of the course of treatment with the oral drug.

It should be noted, however, that the comparative costs of these 2 treatment strategies might vary substantially depending on the perspective from which costs are assessed—whether it be the hospital, the patient, the insurer, or society. For example, if the oral course of treatment occurred after the patient was discharged from the hospitalization in which PTCA plus insertion of a bare-metal stent was performed, the cost of that strategy to the hospital would be far less, the cost to the patient would likely be far greater, and the cost to the insurer might or might not differ relative to the cost of using a drug-eluting stent.