DRUG-ELUTING STENT TASK FORCE:
Final Report and Recommendations of the Working Committees on Cost Effectiveness/Economics, Access to Care, and Medicolegal Issues

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Coronary artery disease remains a major health problem worldwide. Since introduction of percutaneous transluminal coronary angioplasty (PTCA) and stents, much progress has been made. Percutaneous coronary intervention (PCI) however, has been limited by restenosis (repeat obstruction of arteries which previously have been treated), with introduction of drug-eluting stents (DES) in April 2003 a major breakthrough in preventing restenosis. In March 2003, The Society for Cardiovascular Angiography and Interventions (SCAI) published a position statement on the clinical implications of DES, recommending an evidence-based adoption strategy. Subsequently, in May 2003 SCAI formed a multidisciplinary DES Task Force to address the significant non-clinical ramifications posed by DES: medicolegal, financial and access to care. The Task Force included representatives from physician societies, industry, academia, the reimbursement community and health policy organizations. The resultant report presents analyses, options and recommendations regarding those non-clinical issues, based on the collective experience and knowledge of the Task Force members. The Task Force trusts that this report will be of value to the diverse constituencies involved with introduction of this important new technology.
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EXECUTIVE SUMMARY

Coronary artery disease remains a major health problem throughout the world. Since introduction of percutaneous transluminal coronary angioplasty (PTCA) in 1978 and stents in the early 1990s, much progress has been made in treating atherosclerotic obstructive coronary artery disease. Percutaneous coronary intervention (PCI) however, has been limited by restenosis, i.e., repeat obstruction of arteries which previously have been treated. Introduction of antiproliferative drug-eluting stents (DES) in April 2003 is a major breakthrough in preventing restenosis after initial PCI.

In March 2003, The Society for Cardiovascular Angiography and Interventions (SCAI) published a position statement on the practice and health care delivery implications of DES. * The position statement noted that DES have shown significant reductions in restenosis in each group in which they have been formally tested, also noting there exist other sub-groups for which there are limited data. In the statement, SCAI recommended an evidence-based adoption strategy recognizing that physicians are concerned about offering the best possible patient care.

The position statement noted that DES pose significant non-clinical ramifications: medicolegal, financial and programmatic, recommending that a multidisciplinary task force address those issues. In May 2003, SCAI formed a blue-ribbon Task Force, including physician societies, industry, academia, the reimbursement community and health care research/policy organizations.

* The position statement is included in full in the end notes to this report.
The Task Force formed working groups in three areas: economics, access to care and medicolegal issues. The report that follows discusses each of these three areas:

Cost-Effectiveness/Economics. This section addresses economics from several perspectives:

- The hospital: DES are expected to significantly alter the treatment of coronary artery disease (CAD), shifting more resource-intensive patients into DES procedures and expanding the percutaneous treatment option to patients who did not have this choice before. The economic impact on hospitals involves a complex interplay of variables: DRG payment rate, average stent use per procedure, revascularizations and coronary artery bypass grafts avoided, and pricing.

- Society/the Health Care System: Patient selection for DES implantation is an evolving issue that should be based on careful assessment of therapeutic benefit, adverse events, generalizability to subgroups and indications, as well as cost-effectiveness results.

- The Physician: Physicians are inherently concerned about their patient’s safety and quality of life. Where the evidence demonstrates a benefit, that must be a primary consideration; where no data exists, a reasoned judgment must be made. In all cases, the potential benefit to the patient is the foremost consideration.

- Industry: The pricing of any new medical technology is a complex issue that involves assessing the intrinsic value of the technology in relation to other alternative
therapies available for treating the medical condition, the cost of manufacture, the need to recover research and development expenses over a finite period of time, as well as ongoing costs.

- **Payors:** Real world experience data demonstrate that DES are already impacting beneficiaries, hospitals, clinicians, the Medicare program and other insurers. Practice patterns are still emerging and are subject to supply, clinical confidence and reimbursement constraints. It is critical that changes in Medicare’s DRG relative weights and rates keep pace with evolving treatment patterns so that financial incentives to hospitals are appropriately aligned. By doing so, CMS will help ensure that Medicare beneficiaries receive care that is driven by clinical rather than financial incentives. The report makes specific recommendations to CMS accordingly.

**Access to Care.** Because of the now well-documented lower rate of in-stent restenosis with DES, there are theoretically more lesion subsets to which interventional revascularization technology can be applied. As clinical research continues, the appropriate indications for DES use will likely expand. As clinical indications expand, there will be increased demand for DES availability, design modifications and affordability. Because of the high cost of these devices and limitations on supply, access to them may be limited in several ways. Possible solutions to these concerns:

- Interventional cardiologists are eager to educate themselves about this important new technology, and all stakeholders have a vested interest in helping physicians to meet those educational needs.
• The higher costs of DES presents significant, complex challenges for hospital catheterization laboratories and physicians practicing in those laboratories.

• Demand exceeding supply, particularly in the months immediately following FDA approval of DES, has been especially challenging, although this is expected to ease as production increases and additional DES enter the marketplace.

• Relationships of payers to hospital providers can complicate the process by which individual patients receive DES. It is vital that the treating interventionalist be able to make decisions based on the patient’s specific medical condition.

• Local considerations: protocols should be developed to ensure equitable physician access to DES based on medical necessity.

• While non-Medicare insurers have health technology assessment processes in place for determining when a new technology can be covered, the Task Force urges such companies to do so in an expeditious manner.

• Hospitals need to plan for the ongoing introduction of costly new technologies and structure contracts non-Medicare insurers accordingly.
**Medicolegal Issues Surrounding DES.** The initial data comparing the results of DES to BMS have raised a number of medicolegal questions. Concern has been expressed that litigation might be prompted either when a DES was not implanted and restenosis occurred, or conversely if a complication occurs after DES implantation for an unapproved indication. Laws dealing with the definition of malpractice also vary from state to state to some degree.

Physicians who practice evidence-based medicine, actively educate their patients on the risks and benefits of each procedure (informed consent), document this process carefully, and practice what is in the patient’s best interest should avoid most of the medicolegal issues.

**Overall Recommendations:**

- The data surrounding DES are rapidly changing. Physicians must strive to stay abreast of the latest trials and to apply these results in an evidence-based approach to patient care.

- Inadequate supply of DES, or concerns regarding cost should not limit patient access to this therapy. Careful planning, informed consent and meticulous attention to procedural detail should continue to be the standard.

- Ultimate cost-effectiveness may not be determined for some time. Currently, proposed CMS reimbursement is inadequate for multi-lesion or multi-vessel procedures involving DES. Continued efforts to improve DES-related DRG
reimbursement should be encouraged, possibly through data collection on procedure complexity and patient co-morbidities.

- Fears of medicolegal repercussions for either using, or failing to use, DES are unfounded. DES should never be implanted solely to avoid potential litigation.

SCAI and its partner organizations trust that this report will foster dialogue and cooperation among policymakers, the reimbursement community, healthcare providers, industry, physicians and others as they work together to provide optimum patient care.
Introduction

In April 2003, the first drug eluting stent (DES) became commercially available in the United States after years of testing and development. Widespread demand for DES, on the part of both physicians and their patients, had been gathering in the wake of clinical trials demonstrating improvements in restenosis rates compared to bare metal stents (BMS). By combining the advantages of a stainless steel scaffold with controlled release of an anti-proliferative agent modulated by a polymeric coating, restenosis, the most important problem after percutaneous coronary intervention, might be reduced significantly.

Under most circumstances, introduction of a new technology with demonstrable clinical advantages and no apparent additional side effects would be expected to rapidly supercede the previous technologies. Although tested in a limited subset of lesions in controlled, randomized trials, the anticipated benefits of DES in unstudied patients and lesions is expected to result in widespread utilization.

However, DES availability raises substantial economic questions for all segments of the medical community regarding the financial consequences of total substitution of this product for the far less expensive BMS. Additional issues surrounding the medicolegal implications of using or not using this new technology have been voiced. Finally, if substantial disruption of the health care system were to occur as a result of economic or legal pressures, access to DES could be limited for some portions of the population.

In February 2003, anticipating pressures that interventional cardiologists might sense from hospital administrators, patients and malpractice carriers, The Society for Cardiovascular
Angiography and Interventions (SCAI) set forth a position that the decision to use, or not to use, these products should be evidence-based and remain in the realm of the doctor-patient relationship.¹ This Statement further recommended that a Task Force be formed to explore issues surrounding cost-effectiveness, medicolegal consequences and access to care related to introduction of DES to the US market.

The Task Force convened in May 2003 and was designed to be inclusive. Physicians, health care economists, hospital administrators, payors, regulatory experts, insurers and industry representatives were invited to participate. (Appendix A ) The scientific and clinical impact of DES was not discussed, since they have been amply addressed by many recent papers and presentations. This report describes the findings of the multidisciplinary Task Force and is intended to provide a critical review of the issues with recommendations for change.
Cost-Effectiveness/Economics

Overview

Multiple perspectives must be understood to fully comprehend the economics of DES and advise health care professionals. A review of these issues, when combined with the clinician’s review of the scientific and clinical data, should allow clinicians to evaluate cost effectiveness, and to determine optimal DES use in their personal practices. Hospitals, industry, government, physicians, patients and insurers each have independent viewpoints. These differing perspectives will be addressed in turn in this report.

Similar to most other clinical areas and interventions, economic evaluations of percutaneous coronary intervention (PCI) have generally found that newer treatments tend to increase healthcare costs compared to established alternatives (e.g., coronary stenting compared with conventional balloon angioplasty increased long-term costs for most patients, although it is associated with improved outcomes. Yet, stenting does reduce follow-up care costs and is cheaper than surgery). Many factors will determine the economic impact of the DES technology: initial procedural costs and adjunctive procedures; follow-up costs due to reductions in repeat revascularization procedures; Medicare and non-Medicare reimbursement rates; proportion of coronary artery bypass graft (CABG) patients converted to DES; DES adoption rates; increasing complexity of patients being treated with DES (patients with multi-vessel disease and diabetes); indirect costs; and quality of life measures. In subsequent sections, factors influencing cost-effectiveness analysis will be explored to lay a foundation. Subsequently, the different perspectives (e.g., hospital, societal, patient, physician, industry, insurer) will be addressed.
Initial Procedural Costs and Patient Complexity

Initially, the procedural cost of PCI with DES is expected to be higher than prior PCI procedures primarily due to the additional cost of the DES itself. Additional expense may also be ascribed to increases in the resources needed to treat more complex patients that may be candidates for DES. The greater complexity (such as multi-vessel disease and diabetes) and potential resource intensity of cases in which DES may be used comes at an increased cost to hospitals. The cost differential is partially due to the incremental stent price, specific reimbursement issues, an anticipated, but debatable degree of increase in the average number of stents per procedure, and possibly other ancillary procedural costs that likely will be required to treat patients with advanced coronary artery disease (e.g. IVUS, filter devices, glycoprotein inhibitors).

These conclusions are based on the following observations:

- There is an upward trend in patient complexity over the last several years in the type of patients undergoing BMS procedures. ²
- The percent of coronary stenting patients with diabetes, multi-vessel disease, those imaged with IVUS and receiving adjunctive glycoprotein IIb/IIIa inhibitors (all indicators of increasing resource use) has increased. ²
- Over the same time period, there has been a reduction in the incidence of CABG procedures performed on Medicare patients. ³

DES adoption may follow a pattern similar to the adoption of BMS. As coding and reimbursement become available, and as cardiologists become more comfortable with the
procedure, increasingly complex patients whose care requires more resource intensity will be treated. On the other hand, the economic downside is such that there are substantial barriers to universal DES use.

Table 1 (page 59) shows that there has been an overall average increase of 17.3 percent in the incidence of percutaneous coronary intervention (PCI) from 72.0/10,000 Medicare beneficiaries to 89.3/10,000 Medicare beneficiaries over the most recent three years of available data. Simultaneously, CABG procedure incidence rates have been declining (51.0/10,000 to 49.2/10,000). Patient characteristics and technology use among Medicare stenting patients has also changed over the years. The increased utilization of coronary stenting in patients with diabetes and multi-vessel disease, and those receiving IVUS and other adjunctive technology (all indicators of increasing resource use) may also play a substantial role since DES promises to diminish restenosis to a single digit figure, even in these complex CAD cases.

Lesion Complexity and Intensity of Resource Use: A Historical Review of Other Data

United States catheterization laboratory registry data show similar trends in the types of patients treated using BMS and corresponding changes in resource use. For example, data obtained from Goodroe HealthCare Solutions\(^A\) show an increase in the mean number of stents between 2000 to Quarter 1, 2003 from 1.45 to 1.54 stents per case, indicating a trend toward a rising number of stents per case for key populations. The American Academy of Medical

\(^A\) Goodroe HealthCare Data Solutions is a private company that collects detailed clinical and resource use data from approximately 100 cardiac cath labs across the country to assist their clients (cath labs) with clinical and utilization reporting on diagnostic and therapeutic procedures performed in the lab.
Administrators has publicly stated, “It is highly likely the utilization per case on a national level
will accelerate beyond averages of 1.5 to 1.7 per case to well in excess of 2.0 per case.”
However, this assessment is controversial and dependent on how many cases currently being sent
for CABG will be candidates for a multiple DES procedure, and the willingness of physicians to
pursue more complex lesions with PCI. These issues are dealt with in greater detail below.

Initial Procedure Costs

The cost-difference of DES compared with BMS is almost entirely related to the incremental
costs of the stents themselves. The introduction of DES is not expected to change the following
cost components of PCI:

- Diagnostic tests
- Complication rates
- Length of stay in the CCU/ICU and total length of stay

As noted above, the complexity of the procedure, procedure duration, and resource utilization
other than stents (e.g., balloons, guiding catheters) may or may not change significantly,
depending on the extent to which patients with complex and multivessel disease now receiving
CABG become candidates for DES procedures. The use of IVUS, multiple balloons for pre and
post dilation, and other adjunct equipment and devices may increase substantially. Also, the
optimal use of glycoprotein IIb/IIIa receptor blockers in DES cases is entirely undetermined and
a matter of widespread debate.

Stent Price
The current list price for the CYPHER sirolimus-eluting stent (the only stent approved by the FDA as of October, 2003) is $3195/stent. With volume discounts and rebates to many centers, the average selling price is expected to be \( \sim \) $3000/stent. Thus, when compared with an average sales price of $1000/BMS, the incremental cost of each DES is expected to be \( \sim $2,000 \). Prices for both DES and bare stents are expected to fall, however the differential is expected to remain relatively constant. In order to estimate the impact of DES on initial treatment costs, one must also consider that many procedures require the use of more than one stent. Although national estimates are not readily available, data from several clinical trials and single center studies indicate that mean stent use is \( \sim 1.4 \) per procedure. This varies widely from hospital to hospital, with some centers reporting use of nearly 2.0 DES stents per procedure. A recent analysis by Ernst & Young based on 119 representative centers submitted to CMS concluded that 1.5 stents per procedure was usual at this time. The role of stent supply, physician comfort, and reimbursement in confounding these results is unknown, an increase of stent usage was predicted by survey respondents.

Thus, conversion of the current PCI population from BMS to DES would be expected to increase initial hospital costs by an average of \( \sim $2800 \)/patient treated, if 1.4 stents/procedure @$2000/stent, is used for the calculation, but may be \( \sim $3000 \)/patient treated if 1.5 stents/procedure @ $2000/stent is used. Both these values may underestimate the true number of stents used per procedure. Preliminary data from NCDR (with more than 300 labs reporting) indicates that less than 1.5 stents are being used per procedure. (W. Powell, personal communication) Existing data suggest that the long-term results of DES may be optimized by implanting somewhat longer stents, rather than multiple stents as is common with current BMS technology. On the other hand, if the use of DES results in an increase in mean stent utilization
per procedure, the net impact on initial hospital costs might be an even greater increase. If actual DES utilization increases to 1.7 stents/procedure due to increased patient complexity, the additional cost/procedure would be ~$3400, and patients with multivessel disease requiring two stents would incur an incremental cost/procedure of at least $4000 over BMS.

In the long run, approval of multiple different DES for use in the U.S. (e.g., the TAXUS stent is expected to get FDA approval in early 2004) will foster competition in this market and it is anticipated that the price of DES will fall. However, it is worth noting that this did not happen for more than five years after the introduction of the bare metal stent and only after three competitors had each been on the market for several years.

Follow-up Costs

Most data regarding the impact of restenosis on long-term costs after PCI are derived from clinical trials, single-center series, and recently the Medicare population. Although these data may not represent the entire population of patients undergoing PCI, they provide several important insights. For example, in the ESPRIT trial, restenosis added an average of ~$1,700 to each patient initial procedure cost during the first year after implantation. In the Medicare population, the added cost per patient undergoing PCI was ~ $2,700.

Although DES have higher acquisition costs compared with BMS, total treatment costs (initial and follow-up costs) will depend on cost offsets associated with reduced restenosis rates and reduction in the need of repeat revascularization procedures.

Based on current DES costs, even if DES were to completely eliminate restenosis, the resulting follow-up cost savings ($2,700/patient treated, based on Medicare population data) would not fully offset the higher costs of the stents themselves. Given current levels of efficacy
(~70%-80% relative risk reduction for target lesion revascularization [TLR], i.e. clinical restenosis), more modest cost offsets are likely.

**Conversion of Current CABG Procedures to DES**

The introduction of DES is expected to result in conversion of current CABG procedures to stenting with DES. Since current reimbursement rates for CABG and PCI (even with DES) differ by ~$15,000, conversion of even a modest proportion of current CABG procedures to PCI may have a favorable impact of health plan’s expenditures, at least over a 1-2 year time horizon. While the true rate of such conversion is difficult to project, at least one retrospective study suggests that a 21% conversion rate might be expected within 1-2 years after the introduction of DES.4

**Indirect Costs And Quality Of Life**

Current analyses focus on direct medical costs (i.e., repeat procedures, hospital admissions, diagnostic tests and medication use). Although coronary restenosis has a relatively short-lived impact on quality of life, it may also be associated with indirect costs such as transportation costs and productivity losses on the part of both patients and caregivers. Inclusion of these costs in an economic analysis will result in a greater offset of the higher initial costs associated with DES. The impact of DES use on quality of life is based on the assumption that DES significantly reduce restenosis and its attendant complications. For quality of life assessment, only clinical restenosis is of concern, and based on results from clinical trials, the DES will prevent clinical restenosis in approximately 70% of patients compared to bare metal stents.
In the overall population there is an inherent risk of restenosis that can be predicted by several well-defined clinical and lesion-based risk factors, with the presence of diabetes, vessel size and lesion length being the main determinants. Based on these factors, the risk for clinical restenosis in de novo BMS stented lesions may vary from as low as 4% up to approximately 30%. Clearly, the potential impact of DES on quality of life is much greater in the higher risk groups (see section on Societal Perspective).

The impact on quality of life can only be assessed in the context of the clinical outcome for an episode of restenosis, the risk for repetitive restenosis that does not respond to repeat intervention with or without brachytherapy, and the risk of recurrent symptoms that are not attributable to restenosis of the target lesion. The major clinical outcome of restenosis is recurrent stable angina, although the presentation may be unstable angina in some patients and total occlusion or acute myocardial infarction infrequently. Repeat percutaneous intervention generally provides a high rate of acute success and relief of these symptoms. Long-term success is lower for repeat procedures. Unfortunately, re-recurrence still occurs in 25-30% of patients even after vascular brachytherapy. Fortunately, subsequent percutaneous intervention is again successful in many of these patients providing a high probability for long-term success and resulting in recalcitrant restenosis in only about 2-3% of patients. Restenosis of the target lesion and these related events are the main effectors of quality of life measures during the first year after stenting. After the first year clinical events continue to occur, but are due to progression of atherosclerosis at other sites rather than restenosis of the target lesion. Moreover, the impact of repeat DES for in-stent restenosis after BMS or DES has not been established.
DES Adoption Rate

Currently, over 80% of PCIs procedures involve the use of a stent. The budget impact of introducing DES will depend on the conversion rate from BMS to DES (i.e., adoption of the DES technology by medical centers and physicians). Currently, the adoption levels of DES in European countries range from less than 10% to greater than 60%. This uptake is mainly constrained by reimbursement policies/incentives. However, based on experience with other technologies (i.e., BMS, implantable defibrillators), the adoption rate in the US is expected to be greater and occur faster when compared with other Western healthcare systems (Europe and Canada).

Other Factors

Currently, many patients remain unsuitable for PCI because of diffuse disease or technically unsuitable coronary anatomy. Therefore, this projection is limited to the type of patient population enrolled in recent clinical trials (e.g., SIRIUS, RAVEL, TAXUS IV), and the indications approved by the FDA.

The use of DES in patients with higher restenosis risk (i.e., diabetic patients, long lesions, small vessels, bifurcations) may also result in cost-savings to the healthcare system, even at current DES prices.

United States Expenditures

Recently, Lemos and colleagues estimated that ~1,000,000 PCI are performed each year in the US and ~80% of these patients receive stents⁵. Assuming a 100% usage of DES, an average of
1.5 per procedure, and an incremental cost of $2000/stent, an extra $2.4 billion would be added in procedural costs per year ($2000 * 1.5 * 800,000). Part of this cost will be offset due to reduction in the number of repeat interventions and coronary artery bypass grafts avoided. Thus, unrestricted use of DES may increase US costs by ~$1.5 billion each year. This analysis fails to fully capture the cost savings achieved through avoided repeat revascularizations and surgeries. It also may represent an overestimate of the true budget impact because in the current environment many patients remain unsuitable for PCI because of diffuse disease or technically unsuitable coronary anatomy. Nevertheless, the efficacy of DES for treating complex lesions, in stent restenosis and vein grafts has yet to be determined in clinical trials. In addition, a 100% adoption rate was assumed, while the true adoption rate is expected to be lower and may be restricted by reimbursement policies and other financial incentives.

Economic impact on hospitals

The Impact of DES Adoption on Global Hospital Finances

DES are expected to significantly alter the treatment of coronary artery disease (CAD) by shifting more resource-intensive patients into DES procedures and expanding the percutaneous treatment option to patients who did not have this choice before. Although the Centers for Medicare and Medicaid Services (CMS) established two new diagnosis-related groups (DRG) to account for added resources and pay for DES procedures, payment levels are still inadequate (see “Payor Perspective”). Many non-Medicare payers use Medicare as a reference in setting their own hospital payment levels. Medicare patients typically represent between 45-50% of all hospital coronary stenting patients. The high proportion of Medicare patients and inadequate Medicare reimbursement could significantly reduce hospital profits.
At the CathLab Digest Annual Symposium on Cardiovascular Care in June 2003, the potential 1-year financial impact of DES adoption on hospitals for inpatient revascularization procedures was examined, given the current reimbursement environment. The authors found that the average hospital loss per initial DES patient was $1,389 when all sources of payment were considered, whereas BMS and CABG procedures generated $285 and $1,283 in profit respectively. As DES adoption increases and/or the average number of stents per procedure increases, hospital profits decrease. Profits may be maintained until the average number of DES per procedure reaches 1.8 and the conversion from BMS and CABG are over 80% and 15% respectively. Hospital profits were also negatively impacted as private payer payment levels (based on a percentage of Medicare) decreased. Hospital profits increased as the percent of Medicare patients treated decreased.

Clearly, the current Medicare hospital reimbursement levels for DES procedures were not adequate to cover the costs (cost = $18,241 vs. payment = $14,713) for the hospitals in this study. Payments from other payers are not likely to make up for these losses. During the first year that DES are on the market, hospitals may lose 47.2% of their profits across all revascularization procedures. However, hospitals may not incur actual losses on coronary revascularization procedures if the average number of DES per procedure does not increase to 1.8. Though the impact of DES on hospital finances will vary by hospital, key drivers of financial impact for all hospitals appear to be private payer reimbursement levels, Medicare payer mix, hospital costs and the average number of DES used per procedure. Medicare has reduced the payments for inpatient DES procedures performed on patients with an acute myocardial infarction in 2004.
Pricing

Medicare agreed before DES were released to pay an additional base amount of approximately $1800 over and above the BMS procedure reimbursement rate. Two new DRGs (526 and 527) were established. However, all DRGs are subject to adjustment so that no two hospitals receive the same amount for any given DRG. The total incremental amount that any given hospital receives for a given DRG may be adjusted upward based on geographic location (cost of labor differences), indirect medical expenses (I.M.E.) for teaching institutions, and the percentage of indigent patients treated (D.S.H.). The net result is that a major teaching institution in an urban center that treats a substantial number of indigent patients may be paid as much as 50% more per procedure than a rural hospital. The average national upward adjustment is about 22%. Thus, the average incremental reimbursement for a DES DRG above the BMS DRG reimbursement is about $2,200. This means that since the incremental cost of the DES is ~$2,000 (range, $1800-2200) per stent more than the BMS ($3000 vs. $1000), 1.1 DES per procedure would be covered by this incremental payment ($2,200/$2,000). However, additional DES use above this average rate of 1.1 stents per procedure would result in a loss of revenue to the hospital compared to a BMS procedure. Thus, the interventional community finds itself in a situation where the cost of a universally acknowledged technological advance may actually result in less revenue for the hospital in which the procedure is done.

The DRG system also reimburses on a per procedure basis, irrespective of how many stents, catheters, guidewires or ancillary drugs or devices are used. Thus, if everything else is held constant, hospitals that have a high per procedure stent usage will have lower profitability per procedure than those that have low average per procedure stent usage. Finally, it is likely that high volume institutions will be paying a lower price for all of their technologies, including
DES. Thus, the economic impact on a given hospital involves a complex interplay of these variables: DRG payment rate, average stent use per procedure, avoided repeat revascularization and CABGs and price of the DES.

The Societal/Health Care System Perspective

Optimizing the use of DES: insights from cost-effectiveness analysis

Patient selection for DES implantation is an evolving issue that should be based on careful assessment of therapeutic benefit, adverse events, generalizability to various subgroups and indications, as well as cost-effectiveness results. Although from the patient’s perspective, DES would ideally be used to treat all lesions for which there was even a small absolute benefit, in the short-term, it is likely that the high cost associated with this technology may force hospitals and interventional cardiologists to limit utilization of DES to those high-risk patients who would be expected to derive the greatest clinical benefit. Cost-effectiveness analysis provides a useful framework that can be used to support the development of such treatment guidelines.

Cost-effectiveness analysis is a method for comparing the expected benefits of a medical technology with the net cost of the technology. This relationship is expressed in terms of an incremental cost-effectiveness ratio, which is calculated by dividing the incremental cost of the treatment being evaluated (relative to standard-of-care), by its incremental benefits (also compared with standard-of-care):

\[
\text{Incremental Cost-Effectiveness Ratio} = \frac{\text{Cost}_{\text{New}} - \text{Cost}_{\text{Standard}}}{\text{Effectiveness}_{\text{New}} - \text{Effectiveness}_{\text{Standard}}}
\]
In general, costs are measured in monetary terms, while any valued clinical outcome may be used to measure the health benefits. Although any clinically relevant outcome measure can be used in the denominator of a cost-effectiveness ratio, the standard approach is to assess long-term health outcomes in terms of quality adjusted life years (QALYs). The QALY concept uses years of life in perfect health as a common metric to value both mortality (i.e., life expectancy) and quality-of-life. QALYs are calculated by weighting each time interval in a given state of health by its “utility”—a value between 0 and 1 that reflects the individual’s preference for that health state relative to perfect health (utility=1) and death (utility=0)\(^8\).

Once the cost-effectiveness ratio is calculated, it is typically compared with other therapies using the same metric in a “league table”. The threshold for determining whether a therapy is economically attractive varies with the available health care budget. In the United States, for example, cost-effectiveness ratios < $50,000 per QALY gained are viewed as favorable, and cost-effectiveness ratios between $50,000 and $100,000 per QALY gained are frequently considered to be in a “gray zone”. In contrast, a cost-effectiveness ratio greater than $100,000 per life-year saved is viewed as economically unattractive in virtually all health-care systems (including the U.S.)\(^9\).

Although the use of QALYs as an outcome measure in cost-effectiveness analysis is valid in theory, several pragmatic issues limit the usefulness of this endpoint for valuing treatments aimed at avoiding coronary restenosis after PCI. Specifically, there is no evidence that restenosis affects short- or long-term survival after PCI\(^10\). Therefore, one would not expect treatments whose sole benefit is a reduction in restenosis (such as DES) to improve population-level life expectancy. Although it is well-recognized that restenosis is associated with reduced quality of
life (at least in the short- to intermediate-term)\textsuperscript{11, 12}, empiric data as to the overall impact of restenosis on quality-adjusted life expectancy are limited.

Given these limitations, it has been common for economic evaluations of treatments that reduce restenosis to be presented in terms of a disease-specific cost-effectiveness ratio\textsuperscript{13, 14, 15}. In the case of interventions aimed at reducing restenosis, the most logical metric would be the cost per repeat revascularization avoided. The primary limitation of this endpoint is that it is specific to the field of interventional cardiology and cannot be compared with cost-effectiveness ratios for other conditions, or against cost-effectiveness analyses using different outcome measures. Thus, determination of an appropriate cost-effectiveness threshold may be challenging. Within a specific healthcare system, however, comparison with other established (and reimbursed) technologies that can prevent coronary restenosis might serve as a benchmark. For example, within the U.S. healthcare system, several technologies with cost-effectiveness ratios <$10,000 per repeat revascularization avoided (e.g., brachytherapy for in-stent restenosis, elective coronary stenting vs. balloon angioplasty) have been widely adopted and reimbursed by most third-party payers\textsuperscript{14, 16, 17, 18}. These observations thus suggest that novel therapies with cost-effectiveness ratios < $10,000 per repeat revascularization avoided may be considered reasonably attractive within the U.S. healthcare system.

In order to evaluate the potential cost-effectiveness of DES within the U.S. healthcare system, Greenberg and colleagues have developed a detailed, decision-analytic model to project the long-term costs and clinical outcomes of patients undergoing single vessel PCI\textsuperscript{19 20}. Data for this model were derived from a variety of sources. Outcomes of conventional stent implantation were based on a clinical trials database that currently contains 1-year data on more than 7000 patients undergoing PCI with conventional stent implantation\textsuperscript{21}. Costs of PCI, its complications,
and treatment of restenosis were based on pooled data from several multicenter trials of contemporary PCI involving more than 3000 patients\textsuperscript{14,15, 22, 23, 24, 25}. Key assumptions of the model were based, to the extent possible, on empirically derived data and included an average target vessel revascularization (TVR) rate for bare metal stents of 14\% \textsuperscript{26, 27}, an 80\% reduction in TVR with DES\textsuperscript{28, 29}, an incremental cost of $2,000 per DES, and utilization of 1.4 stents per single-vessel stent procedure on average\textsuperscript{24}. Clearly, even small deviations from these assumptions may have important implications on the economic analysis and its conclusions. Recently, the prices for DES have been lowered, however the prices for BMS have also been reduced resulting in no change for the incremental cost of DES.

Under these baseline assumptions, this model projected that over a two-year follow-up period, overall medical care costs with DES would be ~$900/patient higher than with BMS, with an incremental cost-effectiveness ratio of ~$7,000 per repeat revascularization avoided. Sensitivity analyses demonstrated that treatment with DES would be cost saving (i.e., higher efficacy at lower cost) for patients with a bare metal stent TVR rate >20\% and cost-effective (i.e., cost-effectiveness ratio <$10,000/repeat revascularization avoided) for patients with a bare metal stent TVR rate >12\% (Figure 1, page 62). (see PowerPoint file provided separately)

Further insight into the ideal patient population for implantation of DES may be derived from statistical models to predict restenosis after implantation of bare metal stents. In general, these studies have identified smaller reference vessel diameter, greater lesion length, and the presence of diabetes as consistent predictors of both angiographic and clinical restenosis after conventional stent implantation\textsuperscript{21, 30}. A predictive model for clinical restenosis after stent implantation based on these 3 predictive factors is displayed in Table 2 (page 60). By combining these predicted restenosis rates with the previously described cost-effectiveness model, it is
possible to estimate the cost-effectiveness of DES for a variety of specific patient and lesion characteristics. This approach demonstrates that compared with conventional stents, DES would be cost saving for only a modest proportion of the current PCI population. On the other hand, these models also indicate that DES should be economically attractive (i.e., cost-effectiveness ratio < $10,000 per repeat revascularization avoided) for most diabetic patients and for non-diabetic patients with smaller vessels (reference vessel diameter < 3.0 mm) and longer lesions (lesion length > 15mm).

In interpreting the results of these cost-effectiveness analyses, several important points must be kept in mind. First, the results of these cost-effectiveness analyses are critically dependent on the underlying assumptions regarding the incremental cost of DES compared with BMS as well as the number of stents per procedure. If the cost of DES relative to BMS decreases substantially in the future, the cost-effectiveness of DES will improve substantially and the ideal patient population will expand accordingly. On the other hand, if stenting techniques change with adoption of DES such that device utilization increases (despite financial disincentives), the cost-effectiveness of DES on average may be somewhat less favorable than has been projected.

In addition, it should be noted that the preceding analysis applies only to the population of patients who currently receive PCI. There are several reasons for this approach. First, this is the only group of patients for whom reasonable estimates of treatment efficacy are currently available. No clinical trials have been performed testing DES vs. medical therapy for coronary artery disease in patients who are not currently considered for revascularization. Similarly, there are no data yet available on either short- or long-term cost and outcome comparisons of bypass surgery vs. PCI with DES. Moreover, even if DES do result in some shifting of patients from
either medical therapy or CABG to PCI, it is likely that the vast majority of DES patients will be
drawn from the current PCI cohort. Thus, insights from a direct comparison of BMS vs. DES
will directly apply to the largest patient population.

Finally, the use of lesion-specific data for cost-effectiveness projections implies that one
would be willing to apply DES to specific patient cohorts in a targeted manner. If society is
unwilling to accept such targeting (which might also be considered “rationing”), however, the
cost-effectiveness analysis must consider use of DES as an “all or none” proposition. Given the
current clinical restenosis rate of ~14% among PCI patients, this “societal” analysis would
suggest that use of DES for all patients who currently undergo PCI (assuming similar levels of
effectiveness) would be economically attractive compared with current standard of care.

The Patient’s Perspective

Views on appropriate utilization of any new therapy are based on the observer’s
interpretation of relative risks and benefits. For clinicians, health care economists and other
scientists, this interpretation is usually based on careful review of the scientific literature and
includes assessment of therapeutic effect, adverse events, generalizability to various subgroups,
and cost-effectiveness data. Most patients do not have access to or the training necessary to
interpret this level of data and must base their assessment on other sources. In the modern era,
the news media and direct patient advertising represent the major sources of this information.
Given the overwhelming positive results of most of the DES studies reported in peer-reviewed
journals and the media response to these results, it is not surprising that patients believe that DES
should be used for all patients and for all indications.
This enthusiastic view from the patient’s perspective is not tempered by issues such as relative benefit for a given lesion class or overall cost-effectiveness. As with other health care consumption in most western countries, relative benefit is not a concept for consideration by the individual patient who feels a therapy that is perceived to be better by any degree should be provided regardless of cost.

In the case of DES, this is complicated further by the lack of patient understanding as to just what the benefit is. From the perspective of many patients, their current illness is caused by a “blocked” artery that can be “cured” by placement of a stent, but which may recur within only a few months. Most patients do not appreciate the concept that any stent is a temporary treatment for relief of angina but not a cure for the illness. Thus, from the patient’s perspective, failure to place the DES is in effect a denial of the optimal chance for a cure of their heart disease. Initial media reports after release of clinical trial results did little to dissuade this impression.

In summary, from the patient’s perspective, optimal utilization is nearly 100%. This is based on the belief that the DES is equally beneficial in all settings and that it provides a lasting cure rather than a treatment for symptoms.

The Physician’s Perspective

Physicians are inherently concerned about their patient’s safety and quality of life. The SCAI Statement published in February 2003 appropriately laid the ground rules for the physician\(^1\). Judgments about which stent to use should be made based on the clinical evidence together with the patient’s input. Many concerns have been voiced by physicians. (Table 3, page 61). Concern about litigation and about what one’s competition is doing should not be reasons
for using DES. Where the evidence demonstrates a benefit, that must be a primary consideration; where no data exists, a reasoned judgment must be made. In all cases, the potential benefit to the patient is the foremost consideration.

**Industry Perspective**

The pricing of any new medical technology is a complex issue that involves assessing the intrinsic value of the technology in relation to other alternative therapies available for treating the particular medical condition, the cost of manufacturing the product, the need to recover research and development expenses over a finite period of time (based on the expected product life cycle), as well as the ongoing costs associated with royalties or licenses paid to development partners (e.g. for the drug and/or polymer).

In the case of DES, the relevant comparators are the costs of conventional stents and coronary artery bypass surgery, and their respective benefits. Since costs of these alternative approaches differ from country to country -- being considerably lower in Europe and considerably higher in Japan than in the USA -- the relative value in economic terms of DES is likewise different in these different markets. Product life cycles in the field of interventional cardiology also tend to be short (18-36 months on average).

The decision by a company to invest in the development of a new technology presupposes a reasonable return on the investment that is appropriate for the degree of risk involved in developing the technology. Many potential breakthrough technologies fail to recoup their initial investment expenses (e.g. direct myocardial revascularization (DMR); coronary brachytherapy). In terms of both costs and risks, producing small incremental changes in an existing technology is a very different proposition, compared to the costs and risks involved in
developing a totally new class of therapy over seven years, such as DES (which encompasses both the vagaries of device and drug development). The fact that to date there have been many more failed than successful development programs for DES, using drugs such as actinomycin-D, batimistat, dexamethasone, tacrolimus, taxane and paclitaxel when delivered without a polymer-based release mechanism, speaks to the intrinsic difficulty of developing a safe and effective DES.

The reality is that the development and commercialization of a safe and effective DES is a very expensive investment, costing hundreds of millions of dollars. However, unlike the relatively low unit costs of manufacturing many drugs, the cost per unit of manufacturing these drug-device combinations is also high because of the complexity of manufacturing, which in turn may include considerable rejection of product during final inspection.

There is clear and consistent evidence from randomized, controlled trials sponsored by Cordis Corporation (RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS) and the Boston Scientific Corporation (TAXUS I, II and IV) that these DES reduce the need for repeat revascularization after PCI of moderately complex lesions by approximately 60% to 80% -- a remarkably high degree of efficacy -- without significant short and intermediate-term adverse effects to the patient. The value of the technology is best assessed by comparison with current therapeutic alternatives. It is not unusual for new technology to be more expensive than old technology, and to increase the cost of health care. The CYPHER™ Sirolimus-eluting Coronary Stent is cost-neutral or even cost saving to payors and society by the end of one year at an incremental cost of $2,000 per stent versus conventional stents. This conclusion is based on a detailed cost-effectiveness analysis conducted on the SIRIUS trial31, as well as the assessments of private payors. A cost-effectiveness model based on Boston Scientific Corporation’s TAXUS II trial
data demonstrates that the TAXUS DES is also cost-effective\textsuperscript{32}. To what extent these conclusions apply to other DES using different drugs, stent platforms, and polymers, will depend on comparability of the outcomes, product pricing, costs of concomitant drug therapy and cost–offsets due to reduced re-interventions in a representative patient population. Therefore, the issue is \textit{not} that the technology is too expensive, based on its intrinsic value to society. Instead, both Medicare and private payors are gaining the financial benefits of this technology, due to its cost-offsets from reduced re-interventions and shift from CABG, at the expense of hospitals as long as the technology is under-reimbursed. Moreover, managed care organizations may actually gain financial benefit even when the procedure is reimbursed at the current retail price for a drug-eluting stent.\textsuperscript{33}

The solution, from the perspective of industry, based on cost-neutrality of the technology to society and payors, is appropriate incremental reimbursement for DES by all payors. The current reimbursement rates were set before any U.S. cost data were available. The Notice of Proposed Rule Making (NPRM) issued in April by the Department of Health and Human Services (DHHS), indicated that the Centers for Medicare and Medicaid Services (CMS) would consider “the best available data” when setting the reimbursement rates for DES for the next fiscal year, commencing October 1, 2003.

To that end, manufacturers carried out a variety of activities including cost and charge studies, Medicare budget impact modeling, education and mobilization of clinicians, hospitals, health systems and associations to achieve a modification in Medicare inpatient reimbursement for DES procedures. An important longer-term objective is to pursue a DRG categorization effort which appropriately captures DES procedure resource use (e.g., multivessel, complex,
non-complex). This too will only happen if CMS is in receipt of appropriate hospital charge and other data to support DRG construction in this manner.

**Payor Perspective: Medicare DRG Inpatient Payment System**

**Background**

The Medicare Program began paying hospitals for inpatient services on the basis of a diagnosis-related group (DRG) system in October 1983. Prior to this date, hospitals were paid by Medicare based on the costs incurred during each inpatient hospital stay. There was little incentive for hospitals to control the cost of providing services under this cost-based system. The longer a patient stayed in the hospital and incurred more costs, the higher the hospital payment. Under the DRG system, hospitals are paid a flat rate for clinically similar and resource intensive hospitalizations, regardless of actual costs or length of stay in the hospital. Each inpatient admission is assigned to one of 500+ mutually exclusive DRGs on the basis of ICD-9-CM diagnosis and procedure codes submitted on hospital claim forms (UB-92s). CMS calculates “relative weights” for each DRG on the basis of the relative resources required for each DRG hospitalization as represented by billed charges on the UB-92. Payment is then calculated based on the relative weight for the DRG multiplied by the “base rate” or the dollar amount that converts the DRG weight into a payment amount. A hospital may receive additional payments based on its geographic location, teaching status, proportion of low-income patients, or if an individual case meets a certain cost outlier threshold. Additional payments may also be made for new technology if certain requirements are met.
Annual Updates to the DRG System

CMS makes updates to the DRG system on an annual basis to reflect changes in treatment patterns, new technology, hospital productivity, inflation and resource use. CMS reclassifies DRGs and recalibrates the DRG weights to address the modifications that are necessary to reflect these changes. DRG reclassification occurs when CMS or an external party believes that cases within an existing DRG or new cases due to the availability of a new treatment modality, require a different (or new) DRG for adequate payment. The reclassification process could include assigning a case to a different existing DRG, or the creation of an entirely new DRG. Typically, the reclassification process includes the analysis of hospital charge data from Medicare claims (MedPAR data). Standardized charges and length of stay for cases with and without a particular procedure or diagnosis are compared to determine whether the difference warrants DRG reclassification. (CMS has not set any threshold amounts or statistical test to determine whether the difference is significant.)

The second part of the update process includes DRG recalibration. The new DRGs and grouping algorithms are established through reclassification, and then the new weights are calculated based the average standardized charges for each new DRG. Standardized charges that are statistical outliers are eliminated and the mean standardized charge for each DRG is recomputed and divided by the national average standardized charge to determine the relative weight for each DRG. Other factors (base rate, geographic adjustment factors, etc.) that are part of the DRG payment system are also updated annually.

After reclassification and recalibration occurs, CMS is required to maintain total inpatient payments at the same level as they would have been prior to DRG reclassification and recalibration. CMS implements the effects of these changes in two ways to maintain budget-
neutrality: 1) DRG weights are normalized with an adjustment factor for that year applied to all DRGs; 2) Permanent adjustment factors are applied (cumulatively each year) to the entire inpatient system by adjusting the base rate.

Medicare Reimbursement for DES Procedures

As noted earlier, CMS established two DRGs to reimburse hospitals for inpatient DES procedures beginning in April 2003. These DRGs (526, 527) mimic those for BMS procedures (separate payment for stenting with and without myocardial infarction), but with each DRG paying about $1655-$1818 more than its corresponding bare metal stent DRG. This differential will be lower beginning October, 2003. The DRG weights assigned to the DES procedures are reduced by approximately 4% and the weights assigned to the BMS procedures by approximately 1%. On average, Medicare payments for bare metal stenting procedures cover at least 90% of procedure costs (not charges). However, Medicare DES payments only cover 75% to 85% of procedure costs, depending on the number of DES used. This payment inadequacy has occurred due to the data and assumptions CMS used in setting the new DRG rates. CMS established the inpatient reimbursement rates for DES procedures by assuming hospital resource use of 1.5 DES per procedure and an incremental cost of $2200 per DES. CMS did not use a realistic US cost per stent nor consider any additional changes in resource use, patient complexity, or conversions from CABG in setting these new DES DRG rates.

However, these limitations must be put in context. Since the advent of conventional percutaneous coronary angioplasty (PTCA), which is reimbursed under DRG 518, only the additional use of bare metal stents (DRGs 516 and 517), intracoronary brachytherapy (DRG 517) and now the use of DES (DRGs 526 and 527) have resulted in explicit incremental
reimbursement when done in conjunction with PTCA in the hospital in-patient setting, and hence have specific DRGs assigned to them. There are no additional explicit payments, and hence no specific DRGs, for many other technologies that have been added to the treatment armamentarium in the catheterization laboratory (e.g. IVUS, rotational atherectomy, embolic protection devices, glycoprotein IIb/IIIa antagonists, cutting balloons, etc.) that may each add approximately $800 to $1,800 to the cost of a given case. Over several years these additional costs may result in a reweighing of the DRGs to a higher level, but this is a slow process.

DES are expected to significantly alter the landscape for treating patients with coronary artery disease. Because restenosis rates in all patient populations seem to be dramatically reduced, the types of patients referred to DES procedures are likely to be more complex than those currently treated with bare metal stenting procedures. Trends include the inclusion of more diabetic patients, an increase in the percent of patients with multi-vessel disease, an increase in treatment for longer lesions, a higher percent of complex lesion treatment and greater migration from CABG to PCI. This will require a level of resource utilization for the provision of DES procedures that exceed the resource use assumptions made by CMS for FY 2003 and 2004.

Similar trends in increasing resource use for BMS procedures have been observed over the years. For example, over time the proportion of patients receiving BMS with diabetes and multivessel disease has increased, as has the average number of stents and balloon catheters used per procedure, and the percent of procedures utilizing ancillary procedures (IVUS, pressure wire, brachytherapy, anti-platelet therapy). Trends such as these result in added costs to hospitals. CMS should account for trends in patient complexity and resource use to establish payments for DES procedures.
After DES are fully adopted in the market, it is likely that the proportion of BMS patients converted to drug-eluting will be close to 90% and the proportion of CABG conversions will be in the neighborhood of 20%. These assumptions are supported by similar adoption rates seen in Europe and published studies that evaluate CABG patient selection criteria for DES. Other adoption rates were simulated by the authors of the study as well. Because 90% of Medicare CABG patients have multi-vessel disease, a greater number of multi-vessel disease patients will be treated with DES due to CABG conversions. The increase in multi-vessel disease patients treated with stenting procedures will cause the overall weighted average number of stents per procedure to increase from CMS’ assumption of 1.5 to 1.7 stents per procedure.

Consequently, although the economic analysis by Lemos and colleagues accurately depicted the financial implications of DES at their introduction, it may underestimate DES usage and clinical utility over the long term. At many levels, including Medicare (in setting its prices initially), the investment community (in valuing the value of the companies producing these devices), and the manufacturers (in developing and marketing the product), there is a sense that there will be major changes in the way medicine is practiced that will make DES a financially attractive device to patient, physician, hospital and the health care system. It is possible that in the future, the widespread adoption of DES in clinical usage may have the following ramifications:

- Even with additional increases allocated to DRG payments for DES, the Medicare Program stands to save money through cost offsets achieved from avoiding repeat revascularization procedures and complications.
• The Medicare cost-savings that could be realized by avoiding these repeat procedures and complications are substantial.

• Although DES procedures may cost more that the BMS procedures initially, these additional costs will be offset through reductions in repeat procedures and complications, and through shifting high cost Medicare CABG procedures to lower cost DES procedures.

• There will likely be cost savings to the Medicare Program even when the actual higher US costs of DES and 1.7 stents per procedure are accounted for in the Medicare inpatient DRG rates for DES procedures.

• The changing complexity of the types of patients with coronary artery disease being treated with minimally invasive approaches will result in an increase in patients with multi-vessel disease treated with DES.

• This shift could result in a 45% increase in the proportion of stented patients with multi-vessel disease (from 20% currently with multi-vessel disease to a projected 29%).

• This conversion is driven by the large percent of CABG patients (90%) with multi-vessel disease who will now be treated with DES.

Summary And Recommendations Regarding the Economic Impact of DES

DES development and adoption represent a revolution in the treatment of coronary artery disease. Real world experience data demonstrates that DES are already impacting beneficiaries, hospitals, clinicians, the Medicare program and other insurers. Practice patterns are still emerging and are subject to supply, clinical confidence, and reimbursement constraints.
Nonetheless, there is little reason to doubt that the early indications of both a more expansive use of DES and a greater intensity of facility resources for their provision, will be reflected in fiscal year 2004 treatment patterns. It is therefore critical that changes in Medicare’s DRG relative weights and rates keep pace with the evolving treatment patterns so that financial incentives to hospitals are appropriately aligned. By doing so, CMS will help ensure that Medicare beneficiaries receive care that is driven by clinical rather than financial incentives.

Proposed Medicare DES Payment Method

To appropriately pay for inpatient DES procedures, CMS should consider an array of possible scenarios to establish DRGs that capture the added resources and costs required for these procedures. For example, CMS might consider differential DRG payments on the basis of patient complexity, such as patients with multi-vessel disease. An increase in the percentage of patients with multivessel disease means that a minimum of two drug-eluting stents per patient will be required. Current DES payment levels may be adequate to cover one DES per procedure, but not two. The first step in establishing a logical payment method would be to group patients according to clinical categories that also reflect differential resource use. For example, patients with multivessel coronary artery disease should be reimbursed at a higher level. The second step would be to establish appropriate DES payment levels for complex and non-complex patients. These rates need to reflect the differential resource use, such as 2+ stents per procedure, the use of IVUS, etc. for complex patients.

SCAI strongly believes that the underlying data and assumptions CMS has incorporated into calculating the DRG relative weights for DRGs 526 and 527 have provided rates that
significantly underestimate the true resource requirements for DES procedures. To address these inaccuracies, we believe the following policy recommendations should be implemented by CMS:

1. Recalibrate relative weights and rates for DRGs 526 and 527 based on current external data that is representative of real world experience and actual US costs. This should be done as soon as possible, but certainly for FY 2005. For the FY 2005 update, CMS should utilize partial year charge data for FY2003 and FY2004 services (which may be confounded by supply limitation and physician learning curves) and external data to recalibrate the DRG weight.

2. In recalibrating the weights for DES procedures, CMS should consider using an average of 1.5-1.7 drug-eluting stents per procedure and an average actual US cost per stent to calibrate the relative weights for DRGs 526 and 527.

3. DRGs for DES procedures need to account for the greater number of stents used and the greater complexity of the procedure in multi-vessel disease patients. Because there may be an increase in the number of multi-vessel disease patients treated with stents through conversions from CABG, these procedures will require more stents and more adjunctive equipment for treatment. CMS should consider structuring DRG payments for these patients specifically to encourage this possibility, as it saves money for the healthcare system overall. To adequately pay for patients with multivessel disease, CMS should establish a rate based on actual usage from appropriate data sources (perhaps 2.7 or 2.8, as in the ARTS Trial).

4. Correspondingly, the average number of DES per single vessel patient would remain at 1.4 stents per procedure. The weighted average number of DES per procedure could
increase to 1.7 with the migration of additional multi-vessel disease patients being treated with DES. CMS should fully cover the incremental costs of DES, and thus should have a mechanism to adjust payment consistent with the number of stents placed.

5. CMS should consider adjusting DRG rates for clinical indication and complexity (i.e., severe LV dysfunction, diabetes). However, the committee recognizes that such adjustments have no CMS precedent in procedural DRGs, although such gradations do exist for some clinical diagnoses, such as acute myocardial infarction that is recognized in the creation of DRG 526.

DES payment rates should accurately reflect the cost of performing these procedures, and encourage appropriate clinical use of DES. CMS should not place financial pressures on hospitals that are not in the best interests of patients especially in this situation where optimal utilization may reduce total Medicare costs.

Drug-Eluting Stents - Access to Care Issues

The recent introduction of DES into clinical practice has presented interventional cardiologists with new opportunities and new challenges. Because of the now well-documented lower rate of in-stent restenosis with these devices, there are theoretically more lesion subsets to which interventional revascularization technology can be applied. As clinical research continues, the appropriate indications for DES usage will likely increase. As clinical indications increase, there will be increased demand for DES availability, design modifications and affordability. As with the introduction of any new medical technology, these devices also present a unique set of new clinical challenges. Because of the high cost of these devices and the
limitations on supply, access to them may be limited in several ways. This section addresses the issues of access to DES and suggests possible solutions.

**Physician Education**

First and foremost, interventional cardiologists must appreciate that the only proven advantage offered by DES is a reduced rate of restenosis in certain lesion subsets. Moreover, these devices do not completely eliminate restenosis. DES have not yet been proven to offer an advantage over BMS in the management of acute coronary complications of interventional therapies. The current first generation DES have not been fully evaluated or designed for deliverability and suitability for direct implantation without predilation. Ongoing studies and product modifications will undoubtedly address these practical implantation issues. The reduced rate of restenosis seen with DES may be jeopardized if these stents are not optimally deployed. Physicians should carefully review the instructions for use and receive proper training for the implantation techniques unique to DES.

Using optimal implantation techniques with BMS can result in single digit restenosis rates in select patient populations. Furthermore, an approved technology already exists for the treatment of in-stent restenosis (intravascular brachytherapy), although the late follow-up after brachytherapy has demonstrated loss of efficacy after 3-4 years. Thus, DES represent an significant evolution in stent technology, not a revolution.

Ultimately, the goal of interventional cardiologists should be to provide optimal patient benefits at optimal costs. There is a spectrum of reduced restenosis rates associated with DES
use dependent upon the characteristics of the lesion being treated and certain clinical characteristics such as diabetes. The most important question then that must be answered by the interventional cardiologist is whether a DES is indicated in each particular clinical situation. This will require an in-depth understanding of the literature as it currently exists and as it rapidly evolves. Consequently, the interventional cardiologist must stay abreast of rapidly developing evidence and the interventional community must rapidly and widely disseminate new knowledge as it becomes available, not only to physicians, but also to the lay public which has demonstrated an unusual and intense interest in these devices.

Factors Affecting Access to DES

Currently, access to DES are affected by the interplay between five factors:

1. The high cost of the currently available DES, and consequently the potential for the purchasing hospital to incur an operating loss on any DES case requiring multiple stents.

2. The inability of the DES manufacturer to meet the current demand for the devices.

3. The relationship of payers (public and private) with hospital providers, and the natural resistance of payers to pay the increased cost for these devices.

4. Pressures exerted at a local level within each hospital provider by individual interventionalists to have access to DES.

5. Processes utilized by non-Medicare insurers to determine if their customers will have access to a particular DES.
1. High cost of multi-DES cases

   The only approved DES (Cypher, Cordis Corporation) as of October, 2003 was released with a purchase price of $3,195 per stent, roughly 2.5-3 times the cost of BMS. When multiple stents are needed in a given patient, device costs can be quite high. The interventional cardiologist will need to continuously evaluate which patients with multivessel disease should have multiple DES placements and which might be best served by coronary artery bypass grafting. In a worst-case scenario, if “front-end staging” of DES occurred, the reimbursement for the total interventional management of the patient would increase. Perversely this could result in an increased number of interventional procedures to which certain patients are subjected, and the associated costs. Should either of these two scenarios occur with any significant frequency, cost-effectiveness analyses will be spurious. Paradoxically, at least in this multivessel patient subset, DES may then increase the total cost of care relative to BMS, or by consciously avoiding their use, result in a selective restriction to access and suboptimal care. Front-end staging of DES procedures, except for clear medical indications is strongly discouraged.

   Although not yet available in the U.S., the polymer-based paclitaxel-eluting stent (Boston Scientific Corporation) has been released in Europe at a substantial discount to the Cypher stent. Given the similar reductions in restenosis with the TAXUS and Cypher stents, if a similar pricing strategy is employed in the U.S. by Boston Scientific Corporation, there may well be a decided cost advantage for multi-vessel stenting as opposed to bypass grafting, and significantly less pressure to restrict DES usage.

   Finally, some low-volume hospital-providers may find the high cost of DES so prohibitive that it is not economically wise to continue to operate an interventional
catheterization lab. Although we know of no case where this has occurred, if it does, there would clearly be decreased access to all aspects of interventional care for those affected patients.

2. Production/distribution limitations

Cordis Corporation expects to meet inventory demand for DES by late 2003. In the interim, rationing of DES has been necessary. This has taken the form of: 1. Limiting the number of hospital providers that have been brought “on-line”. 2. Rationing the number of devices that “on-line” hospital providers are given. The majority of hospital-providers desiring “on-line” status have received it. At the time this report was prepared, rationing continues, but is improving. It is expected that in the near future, between the increased production capability of Cordis Corporation and the approval of alternative DES, the availability of DES will no longer be an issue. For many patients treated in the initial months following FDA approval, however, DES access was governed by supply on hand, not true need.

3. Hospital provider/payor relationships

Access to DES may also be affected by the relationship of a patient’s insurance carrier to the hospital provider. In today’s medical economic climate, there exist innumerable “preferred provider” relationships between payers and hospitals. Although patients should not be denied access to an optimal therapy based on these relationships, it is easy to speculate that given the high cost of these devices there will be a natural inclination for payers to attempt to limit access to them, particularly if the patient’s hospital-provider is not “on-line”. In this situation, affected patients would have to go “out of network” in order to have access to DES, a situation that usually requires “pre-certification”. This scenario creates the possibility of “denial” unless the payer is satisfied with the indication for DES as opposed to BMS. It is incumbent on the
interventional community to make payers aware that decisions regarding which stent type to use belong to the treating interventionalists.

4. Local considerations

Within any hospital-provider of interventional services there are usually a number of interventional cardiologists providing care. Similarly, there is usually a hierarchy of catheterization lab activity and interventional volume. Invasive lab supervisors and Medical Directors must ensure that all qualified, credentialed interventional providers have access to DES, regardless of their position in the hierarchy. Consequently, we recommend that protocols be developed locally to ensure that DES are used for appropriate indications and that individual providers be given an allocation of DES proportionate to their activity in that lab.

5 Non-Medicare Coverage decision making processes

Many insurers utilize a process to determine if a particular product/procedure should be “covered” as a benefit that can be accessed by the enrollees in the plan. While these processes can take a variety of forms, they essentially involve a determination of the safety and efficacy of the technology at hand and may feature a recommendation by a medical advisory board or other consulting entity. Sometimes, before an insurer will cover a technology, they will require that the device have FDA approval, and that the advisory board pass judgment on the regulatory approval and existence of peer review literature on the technology. While a private insurer certainly has the right to pursue whatever processes it deems appropriate for determining whether enrollees may access a technology, it is critical that when a technology of this import is introduced that the insurer moves in the most expeditious way possible to provide enrollees with timely access to DES as soon as commercially available.
At present, the vast majority of patients (more than 75%) who are privately insured are known to be covered for use of the DES. However, whether “coverage” translates into incremental payment to the hospitals, depends on the particular contract that exists between the individual hospital and the payor. The impact can vary greatly. For example, contracts that are based on a fixed *per diem* amount for each patient (irrespective of the reason for admission) are the most unfavorable for the introduction of any new technology, including DES. Conversely, those that reimburse hospitals on a “percentage of charge” or “new technology carve-out” basis, are the most advantageous. In an era where new technology is likely to continue to be a driver of changing medical practice, it behooves hospitals to critically review their contracts with private payors in order to be able to absorb these technologies most effectively and thereby offer the best quality of care to their patients.

**Summary**

Introduction of DES presents significant challenges in terms of access to care. All constituencies involved have a vested interest in resolving those challenges. The collective willingness to meet this goal is clearly within reach, as this DES Task Force itself has demonstrated by working together effectively on this report. Rapid, widespread and appropriate access to DES require recognition and implementation of the following principles:

- Physician education: Interventional cardiologists are eager to educate themselves about this important new technology, and all stakeholders have a vested interest in helping physicians to meet those educational needs.
• The higher costs of DES presents significant, complex challenges for hospital cath labs and physicians practicing in those labs.

• Demand exceeding supply, particularly in the months immediately following FDA approval of the Cordis Cypher stent, has been especially challenging, although this is expected to ease as production increases and others enter the marketplace.

• Relationships of payers to hospital providers can complicate the process by which individual patients receive DES. It is vital that the treating interventionalist be able to make decisions based on the patient’s specific medical condition.

• Local considerations: protocols within the individual hospital/lab should be developed to ensure equitable physician access to DES based on medical necessity.

• Finally, while non-Medicare insurers have health technology assessment (HTA) processes in place for determining when a new technology can be covered, the Task Force urges that this process be done in an expeditious manner.

• Hospitals need to plan for the ongoing introduction of costly new technologies and structure contracts non-Medicare insurers accordingly.

Medicolegal Issues Surrounding DES

The initial data comparing the results of DES to BMS has raised a number of medicolegal questions. Concern has been expressed that litigation might be prompted either when a DES was not implanted and restenosis occurred (whether or not evidence-based medicine or FDA labeling supported its use), or conversely if a complication occurs after DES implantation for an unapproved indication. Complicating this matter is the fact that the laws dealing with the definition of malpractice vary from state to state to some degree. In general, malpractice is
defined as the deviation from the standard of care within a given community with the result of that deviation causing injury to the patient that otherwise would not have occurred. It is important to remember that this definition not only requires a deviation from the standard of care within a given community, but the fact that this deviation caused injury.

In exploring the definition of malpractice, three important questions need to be answered:

1. What is the standard of care in the community or a similar community?
2. How did the care that was rendered deviate from this standard?
3. Did injury occur as a result of this deviation of care?

Current studies evaluating DES compared to the results from BMS have shown no difference in major adverse cardiovascular events such as stroke, myocardial infarction or death. The main difference to date has been in the incidence of restenosis between these two devices. While restenosis is certainly an unwanted result and leads to the necessity for further intervention it rarely presents as acute myocardial infarction and rarely leads to death. It is unclear whether restenosis itself could be classified as an “injury” that could lead to litigation. However, complications at the time of a second procedure to treat restenosis could fall into this category. There are many examples in the literature evaluating other options of care that have not been discussed as the subjects of litigation, i.e. balloon angioplasty, atherectomy or brachytherapy in the treatment of in-stent restenosis. Much of the current concern over this issue would seem to be exaggerated.
Many health care communities have developed a set of guidelines to assist local interventional cardiologists with the decision to use DES or BMS. These guidelines are based on the current available data, which are limited to only a small number of subsets of patients and lesion types. Following these guidelines does not provide absolute protection from litigation. Performing a procedure falling outside the guidelines could increase litigation risk. While these guidelines are based on evidence-based medicine they should not be misconstrued as a “community standard”. The community standard remains what is actually done in practice and is not based on any set of temporary guidelines. Good judgment on the part of the physician remains a cornerstone in doing what is best for the patient in a world of limited clinical data and resources.

The process by which patients and their families are educated on the risks and benefits of a given procedure, and the manner in which informed consent is obtained remains important factors in minimizing the risk of litigation regarding DES. In most states, a claim of lack of informed consent requires the patient to prove:

1. information exists that should have been provided to the patient in order to obtain informed consent;
2. that such information was not provided to the patient; and
3. that a reasonable patient under the same circumstances would have decided not to consent to the procedure if such information had been provided.

If such information had been provided, in some states, the courts allow the jury to consider the actual patient’s testimony that he/she would have decided against the procedure if the
information had been disclosed. A careful explanation about DES technology and adequate time for answering questions seems even more important than usual since so much has been publicized in the press. A careful explanation and complete documentation remains an integral part of the process for procedures involving DES. Efforts to standardize the consent form may eliminate some ambiguities within a community if a poor outcome occurs and litigation is pursued. In light of recent concerns regarding subacute thrombosis in patients receiving DES, it is important to keep consent information and documentation up to date.

Medicare’s per procedure payment system discourages the use of multiple drug-eluting stents per procedure and this may have unintended and inappropriate effects. Mismatch between the cost for DES and reimbursement provided by the new DRGs has led to concern that multi-lesion (or multi-vessel) procedures may be staged on separate days to avoid the financial loss that occurs when more than one stent is placed during a single procedure. It should be noted that the relative shortage of DES might lead to an appropriate increase in the number of staged procedures --- at least initially. It is also clear that there are medical circumstances where the safest and most prudent course of action may be to perform a staged procedure. Physicians must focus on providing care that is in the best interest of the patient and avoid staging procedures for financial reasons. Medicare officials are aware that their payment structure could encourage inappropriate staging of procedures and they will be monitoring this issue. The medical necessity of staged procedures and what is felt to be in the best interest of the patient should be clearly documented. If staged procedures are not justified, significant legal repercussions could ensue.
In summary, medicolegal issues surrounding DES have been of significant concern to interventional physicians during the months preceding and following introduction of DES. Physicians who practice evidence-based medicine, actively educate their patients on the risks and benefits of each procedure (informed consent), document this process carefully, and practice what is in the patient’s best interest should avoid most of the medicolegal issues.

Overall Summary and Recommendations

For the practicing interventional cardiologist, several highlights and recommendations deserve final mention.

- The data surrounding DES are rapidly changing. Physicians must strive to stay abreast of the latest trials and to apply these results in an evidence-based approach to patient care.

- Inadequate supply of DES, or concerns regarding cost should not limit patient access to this therapy. Careful planning, informed consent and meticulous attention to procedural detail should continue to be the standard.

- Ultimate cost-effectiveness may not be determined for some time. Currently, proposed CMS reimbursement is inadequate for multi-lesion or multi-vessel procedures involving DES. Continued efforts to improve DES-related DRG reimbursement should be encouraged, possibly through data collection on procedure complexity and patient co-morbidities.
Fears of medicolegal repercussions for either using, or failing to use, DES are unfounded and unlikely to materialize. DES should never be implanted solely to avoid potential litigation.

References

1 SCAI statement on drug-eluting stents: Practice and health care delivery implications

INTRODUCTION.
Coronary artery disease remains a major health problem throughout the world. Since the inception of percutaneous transluminal coronary angioplasty in 1978 and the addition of stents in the early 1990s, much progress has been made in the treatment of atherosclerotic obstructive coronary artery disease. Percutaneous coronary intervention (PCI) has eclipsed coronary artery bypass grafting surgery as the treatment of choice for many patients with obstructive coronary lesions. PCI, however, has been limited by restenosis, the incidence of which is highly variable, ranging from less than 5% to over 50% in certain clinical and anatomic subgroups.

While restenosis rates have fallen consistently over the past 10 years due to stent use, ancillary guidance techniques, and possibly adjunctive pharmacology, the recent development of antiproliferative drug-eluting stents (DES) is a major breakthrough in preventing restenosis after initial PCI.

The use of DES in the treatment of obstructive coronary disease will have major beneficial medical impact on the care of patients, but also will create additional Medicolegal, financial, and programmatic ramifications. This statement will provide a preliminary framework to address the multifactorial issues surrounding the introduction of DES into widespread practice.

AVAILABLE DATA
While a number of different drug coatings and binding polymer configurations are under investigation, the majority of clinical data exist for sirolimus and paclitaxel. Randomized trials using both sirolimus and paclitaxel coatings have shown important reductions in target lesion revascularization rates (in the range of 70%-80%). Subgroup analyses are limited, but indicate similar relative success in many traditionally high-risk groups (e.g., diabetic patients, small vessels and lesions located in the proximal left anterior descending coronary artery). Based on these encouraging results, it is widely expected that the U.S. Food and Drug Administration will approve sale of DES devices by early 2003.

It is important to realize that the data for DES are still being collected and analyzed and should therefore be considered preliminary. Data for many challenging subgroups are lacking. Additionally, not all DES results have been favorable. At least three clinical trials with alternative drug formulations have been discontinued after poor or even detrimental effects were observed. The long-term effects of profound inhibition of the healing response following stent implantation are unknown; relatively few patients have been followed for more than 2 years. Finally, many technical questions surrounding DES remain unanswered. Examples include the impact of strut malapposition, the longevity of strut coatings, persistent restenosis, and the implications of DES restenosis.
Early favorable results using bare metal stents (BMS) in conjunction with oral pharmacologic (including sirolimus) adjunctive treatment, and excellent results with intravascular ultrasound (IVUS) or pressure guidance, as well as new strut or coating designs and new pharmacologic agents, continue to be reported. Alternative BMS designs and use of BMS with adjunctive measures have resulted in target lesion revascularization rates near those reported for DES in many lower-risk patient and anatomic subgroups.

Medical therapy for obstructive coronary disease has also advanced. Recent evidence suggests that PCI for some intermediate-severity lesions may be safely deferred (with a low subsequent event rate), especially when coupled with aggressive risk factor modification.

In summary, while DES represent an important advance in the treatment of coronary lesions, available controlled data do not support universal use. Careful attention to proper patient and lesion selection including documentation of physiologic significance may provide acceptable clinical results in many patient or lesion subsets.

**POTENTIAL USES FOR DES**

**Current PCI Candidates.** If DES were applied to current patients, available controlled data would support their use in small to medium vessels (2.25-3.5 mm) with lesions up to 30 mm in length.

**Additional PCI Candidates** DES appear very effective even in traditionally high-restenosis-risk subgroups (e.g., diabetic patients, lesions in proximal LAD, vessels < 3.0 mm). It is reasonable to consider that their availability might eventually prompt expansion of the types of patients who could be treated with PCI. These might include patients with complicated bifurcation lesions, left main coronary lesions, multiple prior restenosis, lesions in saphenous vein grafts, ostial lesions, and multiple lesions. It is important to note, however, that no long-term controlled data currently exist for such applications. Long-term controlled data will be needed to establish the safety and relative benefit in these and other subsets that have not been studied.

**COMPARISON TO CURRENT PRACTICE**

Migration to the use of DES rather than BMS should be technically uncomplicated. DES are functionally similar to their BMS predecessors. Implantation techniques should require little modification. Inventory issues (shelf life, sterility, temperature sensitivity, etc.) should be easily addressed. While initial lengths and diameters may be limited, a full range of sizes will ultimately be available.

**OTHER ISSUES**

**Medicolegal** Concern is expressed by some that despite the lack of long-term scientific evidence to prompt universal application of DES, there may be considerable pressure to use DES for all lesions due to fear of litigation arising from cases of restenosis where BMS were implanted. Use of DES in non-approved applications could also carry risk. Specific issues related to the use (or nonuse) of DES will require much more clinical experience with the use of DES.

**Economic** Current projected pricing for DES is approximately threefold above that for BMS. In some countries where DES are already approved, this differential approaches sevenfold. Given the expected demand for use in existing PCI candidates and the prospect of expansion to new patient subgroups, the economic burden may be substantial. Decreased restenosis and diminished rates of coronary bypass graft surgery will offset some of the expenditures for DES. Governmental agencies have approved an increase in repayment for the use of DES during PCI (to begin in April 2003). The additional payment will be insufficient to cover the increased hospital costs associated with the use of multiple DES per vessel or the treatment of multiple vessels per patient.

Preliminary analyses suggest that DES may be cost-effective in patients estimated to have a clinical restenosis rate with BMS greater than 12%-14%. These calculations are very dependent on the price of the DES. Clinical restenosis probability for individual lesions may be estimated using published tables. Examples include diabetic patients with vessels 3.0 mm, or nondiabetic patients with vessels 2.5 mm. A critical evaluation of the health care economic implications of this exciting but expensive technology will be required.
Programmatic The impact of DES use during percutaneous intervention on coronary bypass surgery is unclear. Some projections include a 10%-50% reduction in surgical case volume. Such dramatic shifts would have profound impact on hospitals, training programs, and reimbursement.

RECOMMENDATIONS
Based on the limited available data and lack of practical experience with DES use, SCAI recommends an evidence-based adoption strategy recognizing that physicians are concerned about offering the best possible patient care. Intervention should be employed only after documentation of the clinical and/or physiologic significance of individual lesions. The patient's physician should make this assessment based on objective evidence.

DES have shown significant reductions in restenosis in each group in which they have been formally tested. These include diabetics, LAD stenoses, small vessels, and both short and relatively long lesions. Some subgroups for which there are few data include patients with saphenous vein graft disease, bifurcation lesions, very small or very large arteries, prior brachytherapy, in-stent restenosis, and acute myocardial infarction. A large spectrum of the coronary disease population will have benefit from reduced recurrence rates after treatment with DES. However, there remain patients for whom this therapy requires further study.

The society also recognizes the role of physicians as important participants in societal health care delivery issues. Interventional cardiologists are highly trained physicians concerned with not only the technical tools of the trade but the important impact that their care has on patient lives and productivity. To address the scientific advances in stent technology without consideration of the societal impact would be inadequate.

SCAI therefore suggests the following: that national databases for collection of interventional data be updated as soon as possible to allow tracking of DES patient outcomes, and that a multidisciplinary task force be appointed to address the financial and medicolegal consequences of DES implementation.

SCAI recognizes that development of this new technology is evolving rapidly. SCAI thus plans to review this document in 6 months, or sooner should new data so warrant.


3 Boston Scientific analysis of Medicare standard analytic files; see Table 1.


33 Clark MA, Lacey MJ, Cohen DJ. Assessing the budget impact of drug-eluting stent adoption in a typical US managed care plan
Table 1: Medicare Trends in Coronary Revascularization Procedures

<table>
<thead>
<tr>
<th></th>
<th>1998</th>
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<th>2000</th>
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<tr>
<td>Procedure rates per 10,000 Medicare Beneficiaries</td>
<td>All Coronary Revascularization Procedures</td>
<td>126.7</td>
<td>132.0</td>
<td>138.5</td>
</tr>
<tr>
<td></td>
<td>CABG Procedures</td>
<td>51.0</td>
<td>50.9</td>
<td>49.2</td>
</tr>
<tr>
<td></td>
<td>All PCI Procedures</td>
<td>72.0</td>
<td>75.8</td>
<td>81.1</td>
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<tr>
<td></td>
<td>Stent Procedures</td>
<td>50.9</td>
<td>59.1</td>
<td>65.3</td>
</tr>
<tr>
<td>Bare Metal Stent Patient Characteristics</td>
<td>% Diabetics</td>
<td>34%</td>
<td>38%</td>
<td>36%</td>
</tr>
<tr>
<td></td>
<td>% with Multivessel Disease (MV)</td>
<td></td>
<td>18%</td>
<td>19%</td>
</tr>
<tr>
<td></td>
<td>MV procedures per 10,000 Medicare enrollees</td>
<td>4.8</td>
<td>6.3</td>
<td>7.6</td>
</tr>
<tr>
<td>IVUS guided procedures per 10,000 Medicare enrollees</td>
<td>2.3</td>
<td>2.5</td>
<td>2.9</td>
<td>3.9</td>
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Data Sources: Medicare Physician Supplier Procedure Summary files; CMS website; Boston Scientific analysis of Medicare standard analytic files.

Table 2. Predicted clinical restenosis rates* based on patient and lesion characteristics.

<table>
<thead>
<tr>
<th>Vessel Diameter</th>
<th>10 mm</th>
<th>15 mm</th>
<th>20 mm</th>
<th>25 mm</th>
<th>30 mm</th>
<th>35 mm</th>
<th>40 mm</th>
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<tbody>
<tr>
<td>Diabetic patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2.5 mm</td>
<td>18%</td>
<td>21%</td>
<td>24%</td>
<td>28%</td>
<td>33%</td>
<td>38%</td>
<td>45%</td>
</tr>
<tr>
<td>3.0 mm</td>
<td>12%</td>
<td>14%</td>
<td>16%</td>
<td>18%</td>
<td>21%</td>
<td>25%</td>
<td>29%</td>
</tr>
<tr>
<td>3.5 mm</td>
<td>8%</td>
<td>9%</td>
<td>10%</td>
<td>12%</td>
<td>14%</td>
<td>16%</td>
<td>19%</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>5%</td>
<td>6%</td>
<td>7%</td>
<td>8%</td>
<td>9%</td>
<td>10%</td>
<td>12%</td>
</tr>
<tr>
<td>Non-diabetic patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.5 mm</td>
<td>11%</td>
<td>13%</td>
<td>15%</td>
<td>18%</td>
<td>21%</td>
<td>24%</td>
<td>28%</td>
</tr>
<tr>
<td>3.0 mm</td>
<td>7%</td>
<td>8%</td>
<td>10%</td>
<td>11%</td>
<td>13%</td>
<td>15%</td>
<td>18%</td>
</tr>
<tr>
<td>3.5 mm</td>
<td>5%</td>
<td>5%</td>
<td>6%</td>
<td>7%</td>
<td>9%</td>
<td>10%</td>
<td>12%</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>3%</td>
<td>4%</td>
<td>4%</td>
<td>5%</td>
<td>6%</td>
<td>6%</td>
<td>7%</td>
</tr>
</tbody>
</table>

* Based on logistic regression analysis of target vessel revascularization among patients treated with single-vessel bare metal stenting and undergoing routine clinical follow-up only (15).
Table 3: Issues Identified by Cardiologists as a Concern in their Decision to Use or Not Use DES

<table>
<thead>
<tr>
<th>Concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reductions in bypass surgery</td>
</tr>
<tr>
<td>Increases in stenting procedures</td>
</tr>
<tr>
<td>Treating more complex patients is difficult</td>
</tr>
<tr>
<td>May change practice patterns due to economic/financial concerns</td>
</tr>
<tr>
<td>Impact on hospital economics if DES is used</td>
</tr>
<tr>
<td>Concern about competitors’ usage of DES</td>
</tr>
<tr>
<td>Concern about malpractice litigation</td>
</tr>
</tbody>
</table>
Figure 1

Relationship between the target vessel revascularization (TVR) rate with bare metal stents and the cost-effectiveness of DESs for single-vessel PCI. This analysis assumes a DES cost of $3,000 per stent, average utilization of 1.4 stents per procedure, and that DES reduce the TVR rate by 80% compared with bare metal stents. Under these assumptions, we would project that DES implantation will be cost-effective (i.e., CE ratio < $10,000/repeat revascularization avoided) for patients with a bare metal stent TVR rate >12% and cost-saving (i.e., better outcomes and lower costs) for patients with a bare metal stent TVR rate >20%.
Appendix: Task Force Members

Subcommittee on cost-effectiveness:

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