In recent years, endovascular services have experienced outsized growth relative to other parts of health care. Patient demographics, technology innovation, and healthy reimbursement rates have contributed to this market expansion. However, what is past is not always prologue, and the outlook for endovascular services is inextricably tied to the economic environment and reform activities impacting health care on a macro scale. This article explores current and future drivers of demand for endovascular services and offers perspectives on evolving provider economics, including the migration toward risk-based payment.

**HISTORICAL GROWTH TRENDS**

Buoyed by favorable patient demographics, technology advancement, and cross-specialty physician interest, the marketplace for endovascular services has grown tremendously in recent years (Table 1). For instance, between 2005 and 2011, angioplasty for lower extremity peripheral arterial disease (PAD) increased 67%, a rate that greatly exceeded overall population growth. Indeed, the entire PAD market has expanded thanks to improvements in catheter, balloon, and stent designs and the advent of wholly new adjunct technologies. However, this is not purely a phenomenon in PAD, as venous angioplasty grew by a similar magnitude, reflecting significant demand for managing arteriovenous (AV) dialysis fistulas and grafts. Venous ablation has experienced the most dramatic growth trajectory, with a 400% increase in just 6 years. Radiofrequency and laser ablation have become foundational technologies in a growing number of hospital and physician-owned clinics serving patients with venous reflux and varicose veins.

There are several notable exceptions to this strong growth trajectory, including percutaneous coronary interventions (PCI) and renal interventions. After years of predictable growth, PCI cases have contracted by 20%. PCI’s troubles began in the mid-2000s, when concerns

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**TABLE 1. VOLUME GROWTH TREND FOR SELECT ENDOVASCULAR PROCEDURES**

Physician claims for select endovascular procedures. Medicare volume, rounded to the nearest 1,000 cases.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>2005</th>
<th>2011</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery stent or angioplasty</td>
<td>465,000</td>
<td>373,000</td>
<td>-20%</td>
</tr>
<tr>
<td>Lower extremity arterial angioplasty</td>
<td>105,000</td>
<td>175,000</td>
<td>67%</td>
</tr>
<tr>
<td>Renal artery angioplasty</td>
<td>21,000</td>
<td>8,000</td>
<td>-62%</td>
</tr>
<tr>
<td>Endovascular aortic aneurysm repair</td>
<td>29,000</td>
<td>33,000</td>
<td>14%</td>
</tr>
<tr>
<td>Carotid stent</td>
<td>13,000</td>
<td>12,000</td>
<td>-8%</td>
</tr>
<tr>
<td>Thoracic aortic aneurysm repair</td>
<td>N/A</td>
<td>4,000</td>
<td>N/A</td>
</tr>
<tr>
<td>Venous ablation (radiofrequency or laser)</td>
<td>25,000</td>
<td>125,000</td>
<td>400%</td>
</tr>
<tr>
<td>Venous angioplasty</td>
<td>187,000</td>
<td>303,000</td>
<td>62%</td>
</tr>
<tr>
<td>Transcatheter embolization</td>
<td>23,000</td>
<td>35,000</td>
<td>52%</td>
</tr>
<tr>
<td>Mechanical thrombectomy</td>
<td>N/A</td>
<td>8,000</td>
<td>N/A</td>
</tr>
</tbody>
</table>
arose about the higher rates of late stent thrombosis and corresponding elevated rates of mortality and nonfatal infarction associated with drug-eluting stents (DES) as compared to bare-metal stents. Although these concerns have been somewhat assuaged by next-generation stent platforms and improvements in antiplatelet therapy practice, PCI has continued to struggle due to questions surrounding incremental benefits over optimal medical therapy in stable patients and recent controversies over appropriate patient selection by some cardiologists.

Renal artery revascularization has experienced an even more precipitous decline in light of conflicting evidence supporting its role in reducing renal dysfunction among stenosis patients. Between 2005 and 2011, 63% fewer cases were performed. The Angioplasty and Stenting for Renal Artery Stenosis (ASTRAL) trial did little to address the controversy, as it showed no significant difference between intervention and medicine. However, supporters of the procedure allege that poor trial design and questionable physician proficiency obscure supportive evidence. Several ongoing trials aim to resolve some of the uncertainties surrounding renal interventions; however, unless clear data emerge to guide patient selection, demand is likely to continue to erode.

CHANGING COMPETITIVE LANDSCAPE

Across the last decade, hospitals have invested heavily to support the endovascular revolution. Today, nearly 2,000 hospitals offer catheter-based revascularization services, representing a 30% increase from 10 years ago. Interest in advanced procedures has been even more dramatic. Across that same period, centers offering aortic aneurysm stent graft repair increased by 115% to nearly 1,300 sites. As a result, endovascular services became more commoditized, and many community hospitals, including those without open heart surgery or coronary interventions, offer vascular services.

Beyond the hospital setting, specialty competition has peaked as advancements in endovascular technology have changed the playing field for physicians with catheter skills. While cardiologists retained approximately one-third of peripheral vascular stent cases between 2000 and 2010, vascular surgeons more than tripled their share to 35% of cases. But vascular surgery’s rise in prominence has come at the expense of interventional radiologists, who lost more than half of their share. In the case of endovenous ablation, vascular surgeons have held onto the majority of cases. While cardiology has gained some ground, it is a minor player, and most other volume is dispersed among a variety of specialists who are offering the procedure as an ancillary service. Indeed, given the low-risk nature of superficial venous disease and less regulation outside of the hospital, most cases are performed in the office setting. Perhaps more unexpected is the outmigration from hospital to physician office of comparatively complex procedures like venous balloon angioplasty and even transcatheter arterial stent placement.

DEMOGRAPHICS FAVOR MARKET EXPANSION

The overall growth of endovascular services has eclipsed virtually all other major procedural categories, yet the market has matured considerably in recent years and is beginning to experience a slowdown in some key sectors. Although three consecutive years of surprisingly low overall health care spending is contributing to softer demand, other specialty-specific factors must be considered when forecasting future volumes. For instance, demographics will continue to favor key endovascular cases, particularly cardiovascular services.
toward the expanding Medicare population. Americans aged 65 and older accounted for 13% of the population in 2008, but this will increase to 20% by 2030.11 Moreover, chronic disease is pervasive in this population, with 78% of Medicare beneficiaries experiencing two or more chronic conditions.12 Many of these patients are treatable with endovascular interventions. In fact, increasing patient acuity has coincided with increasing case complexity, as demonstrated by the shift toward more distant, harder to treat, anatomic regions for lower extremity revascularization (Figure 4).

Notwithstanding population dynamics, prevention efforts have contributed to moderately reduced demand for acute care. Medical prevention has focused on dyslipidemia and hypertension given their significant contribution to overall risk for vascular disease. Statin therapy in particular has been studied for its effects on clinical events and the need for revascularization. Data indicate that statins have led to a relative risk reduction of major coronary events and revascularization of 0.76.13 While less studied in the context of PAD, it is presumed that such benefits accrue to vascular disease outside of the heart. With regard to hypertension, despite an increasing prevalence of high blood pressure, control of hypertension has improved in recent years. Results from the National Health and Nutrition Examination Survey showed that 47% of all people with hypertension had their blood pressure under control from 2009 to 2010, up from 79% in 2001 to 2002.14 However, even with these gains, dramatic increases in risk factors—including diabetes and obesity—will continue to bolster demand for many endovascular services.

TECHNOLOGIES ENABLING GROWTH

Technology advancements have played a pivotal role in improving the safety and efficacy of treatment while simultaneously expanding the endovascular market. Focusing on PAD, the interventionist’s arsenal continues to expand with multiple options for adjunct imaging (intravascular ultrasound and optical coherence tomography), angioplasty (scoring and cutting balloons, cryotherapy), stenting (bare-metal and drug-eluting platforms, and both traditional and fenestrated stent grafts), debulking (excisional and ablative/rotational atherectomy), chronic total occlusions (crossing devices, lumen reentry), and thrombectomy (rheolytic and aspiration). Going forward, novel technologies and clinical techniques will drive additional growth in the endovascular market (Table 2). Four key clinical areas to consider include PAD, valve disease, hypertension, and stroke.

Drug-Eluting Stents and Balloons

In the case of PAD, the November 2012 approval of the first DES with a peripheral indication in the United States (Zilver PTX, Cook Medical, Bloomington, IN)15 has captured the interest of “stenters” and “nonstenters” alike. Today, approximately 45% of interventions for SFA lesions utilize stents, and for many interventionists, DES will simply replace bare-metal stents. However, lower restenosis rates associated with the new technology will also spur adoption of stenting among traditionally more conservative physicians. Although cost may hamper early adoption, Cook Medical is seeking a Medicare hospital inpatient new-technology add-on payment for its DES for 2014.16 Drug-coated balloons (DCB) are further from market reality, but could also significantly alter the treatment paradigm for PAD. Recently published studies have shown greater durability associated with coated balloons over traditional angioplasty.17 It is too soon to tell if DCB treatment will supplant DES, but it has the advantage of avoid-
Transcatheter Aortic Valves

In the history of interventional cardiology, few technologies have elicited the level of excitement surrounding transcatheter valves. Transcatheter aortic valve replacement (TAVR) received FDA approval in November 2011 for use in surgery-ineligible patients with severe aortic valve stenosis and later was granted expanded indications for high-risk operable patients. Thus far, approximately 5,000 patients have been treated with TAVR with the Sapien transcatheter heart valve (Edwards Lifesciences, Irvine, CA). With more than 100,000 severe aortic stenosis patients in the United States not receiving valve surgery, the market potential for TAVR is significant; however, its size may be deceiving. Strict infrastructure, staffing, volume thresholds, and clinical protocol requirements will restrict the number of programs wishing to provide TAVR to between 200 and 300 for the foreseeable future. Economics will also play into the rate of adoption. Currently, the Centers for Medicare & Medicaid Services (CMS) maps reimbursement for TAVR to the existing valve surgery codes. Given the substantially higher supply costs associated with transcatheter valves versus traditional valve surgery, most implanting centers are reporting slim or negative profit margins. Fortunately, CMS will gather claims data across 2013, and it is expected that future payment determinations will be more favorable for TAVR.

Transcatheter Renal Nerve Ablation

While the opportunity for expanding treatment options for severe aortic stenosis is substantial, the market for uncontrolled hypertension is enormous. Of the approximately 68 million Americans with hypertension, several million have stage II, uncontrolled disease. This is the target population for percutaneous renal artery denervation. Although not yet approved in the United States, two key trials have sparked interest in the sympathetic nervous system’s contribution to hypertension. The Symplicity HTN-1 and Symplicity HTN-2 trials have shown sustained improvements in systolic and diastolic blood pressure after the procedure. Benefits may extend beyond blood pressure reduction in hypertensive patients. Some studies have also shown a possible role for denervation to boost the effectiveness of atrial fibrillation ablation, reduce left vertical mass and improve diastolic function, and improve glucose metabolism and insulin sensitivity. It will likely be 2014 before renal denervation has a chance at FDA approval; however, the procedure has the potential for rapid adoption. To-date, occurrence of adverse events has been limited, and barriers to entry are relatively low. The procedure can be performed in a standard procedure suite with modest capital investments, and the learning curve is short. As such, renal denervation could become a substantial market expander for endovascular therapeutics.

Endovascular Stroke Treatment

Each year in the United States there are more than 600,000 ischemic strokes, and up to 120,000 may be amenable to endovascular treatment. Yet even with several recanalization technologies available such as suction thrombectomy and stent retrievers, procedure volume has remained modest. This is due in part to the small number of patients that arrive at hospitals in time for revascularization therapies. Another important factor is the lack of strong, supporting evidence for endovascular therapy over standard treatment with intravenous tissue plasminogen activator. Results from two recently published trials failed to make a strong case for endovascular therapy. In the SYNTHESIS Expansion trial, patients were randomized to endovascular therapy using mechanical clot disruption, retrieval, or intravenous tissue plasminogen activator. No significant differences in clinical outcomes were reported. The Interventional Management of Stroke (IMS) III trial assessed the role of recanalization following thrombolytic therapy but also found no incremental benefit from the added procedure. While future studies will help elucidate the role for endovascular therapy, near-term procedure volumes likely will be suppressed.

INCREASING APPROPRIATENESS SCRUTINY

Notwithstanding the uncertainty surrounding some endovascular therapies, the overall trend has been toward more efficacious treatment options. However, providers are facing greater pressure to deliver high value, appropriate care. Recent publicity surrounding potentially inappropriate placement of cardiac stents serves as a backdrop to efforts by professional associations to refine appropriate use criteria. Although these efforts initially disproportionately focused on cardiac services, it seems likely that this trend will continue across a broader array of endovascular therapies, particularly in instances where treatment alternatives may be available. For interventional cardiology, the net result has been lower rates of referrals and more conservative patient management.
Increasingly, providers must champion appropriateness and take stock of the overall value of services and technologies offered beyond near-term efficacy alone. Regulatory scrutiny, budget constraints, and efforts to deliver patient-centered care have spurred the use of value-based technology criteria. These factors may include clinical and economic comparative effectiveness, market need, effect on quality of life, impact on care delivery efficiency, and level of programmatic investment required.

**Evolving Provider Economics**

For many years, fee-for-service economics have treated procedural services favorably. For hospitals, strong margins on interventions have helped to subsi-

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**Table 2. Demand Forecast for Select Endovascular Procedures (2012–2017)**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Relative Change</th>
<th>Representative Drivers of Growth</th>
</tr>
</thead>
</table>
| Coronary intervention (stent or angioplasty)   | −               | (+) Incremental shift away from bypass surgery; expanding use of primary PCI for AMI cases; encouraging results from DCB studies  
(−) Inroads from prevention and use of optimal medical therapy; significant appropriate use scrutiny |
| Lower extremity arterial intervention (stent or angioplasty) | ++              | (+) Incremental shift away from bypass surgery; expanding base of skilled/interested providers; adoption of DES; advancements in atherectomy technology; encouraging results from DCB studies  
(−) Inroads from prevention; evidence base for DES still building; no approved DCB; gradual increase in appropriate use scrutiny; increasingly saturated market |
| Renal artery intervention                      | −−              | (+) Current dearth of desirable treatment options for renal artery stenosis; potential for new trials (eg, CORAL, RADAR) to elucidate bigger role for endovascular interventions  
(−) Clinical evidence largely not supportive of endovascular therapy; continued concern that payers will restrict reimbursement to approved studies; appropriate use scrutiny |
| Endovascular aortic aneurysm repair            | ++              | (+) Large untreated population; strong efficacy data across wide range of use scenarios; fenestrated grafts, other design enhancements broadening treatable population  
(−) Patients typically found incidentally; relatively low rate of screening; modest inroads from prevention |
| Carotid stent                                  | +/−             | (+) Potential for further shift from endarterectomy; preference for less invasive intervention; ongoing trials may break in favor of stenting for asymptomatic/standard risk cohorts (eg, ACT-1, SPACE, CREST-2)  
(−) Efficacy questioned in asymptomatic cohorts; disconnect between FDA approved indications and CMS payment policy; inroads in preventing internal carotid artery disease |
| Transcatheter aortic valve replacement         | +++             | (+) Large population of severe aortic stenosis patients with suboptimal management; compelling efficacy data; expanding indications for transcatheter therapy; next-generation platforms, new market entrants emerging; gradual reimbursement improvement  
(−) Market restricted by baseline provider requirements; relatively low Medicare reimbursement |
| Venous ablation (radiofrequency or laser)      | ++              | (+) Large population of venous insufficiency patients; patients easy to identify/self-present; currently a lucrative in-office procedure; growing number of providers  
(−) Rapid growth rate makes procedure a target for reimbursement scrutiny; appropriateness use scrutiny, payer standards may be on horizon |
| Renal nerve ablation                           | +++             | (+) Large population of patients with uncontrolled hypertension; encouraging results from initial trials; positive results from other trials likely (eg, Symplicity HTN-3, ARSENAL, REDUCE-HTN); low barrier to entry for interested providers  
(−) Not yet approved in the US; relatively limited base of clinical evidence; drug advancements may limit ablation market |
dize care for relatively poorly reimbursed medical cases. Proceduralists have also fared well, particularly when their allowed charges are compared to primary care and cognitive specialists. However, more recently, CMS has begun to implement policies that will curb Federal health care spending. The impact will be felt differently by provider type and setting.

The trajectory for hospital Medicare reimbursement for endovascular services has been positive. For instance, between 2008 and 2013, inpatient reimbursement for peripheral arterial revascularization increased by 15%. Going forward, payment rates likely will be less generous, particularly with the implementation of health care reform and other mandated cuts. The Affordable Care Act requires annual reductions in the market basket update for inpatient and outpatient services along with a multifactor productivity adjustment.

Although the recent trend line for hospital payment has started from a positive position, the same cannot be said for the physician fee schedule. Across the last 5 years, endovascular specialists have witnessed a decline in average allowed charges. The cumulative estimated impact on total allowed charges for interventional radiologists, cardiologists, and vascular surgeons between 2009 and 2013 has been –14%, –16%, and –7%, respectively (Figure 5).

While the Medicare Sustainable Growth Rate (SGR), enacted by the Balanced Budget Act of 1997, has attracted great attention year after year, last-minute deals from Washington have successfully postponed mandated cuts. The real culprit for lower reimbursement is multifactorial, including changes to work and practice expense relative value unit (RVU) calculations, service bundling, higher equipment utilization factor assumptions, multiple procedure payment reductions, and capping payment for certain non-hospital services at the hospital outpatient level. In addition to these code-specific changes, specialists more broadly have seen lower payment rates due to the elimination of consult codes and policy changes geared toward improving payment for primary care.

Consolidation of individual services frequently performed together into bundled codes has had the most dramatic impact on the work RVUs for endovascular services (Figure 6). CMS has pursued bundling of catheterization, supervision and interpretation, and other components to address misvalued codes and believes the efficiency of providing certain services together should be reflected in the RVUs assigned. First introduced in 2010 for arteriovenous shunt dialysis procedures, bundling now covers 12 relevant procedural domains. The impact on work RVUs can be dramatic. Lower extremity arterial revascularization and certain electrophysiology services have seen average work RVU reductions of 27%. Coronary interventions have held up slightly better with an estimated 20% payment cut.

Insofar as specialty-specific alterations to the phy-

Figure 5. Estimated impact on total allowed charges by specialty based on Medicare final physician fee schedule rules. Rates reflect all rule-making activity except changes to the SGR.

Figure 6. Endovascular services subject to payment bundling and impact on work RVUs for select services. Abbreviations: angio, angiography; AV, arteriovenous; Dx, diagnostic; EP, electrophysiology; IVC, inferior vena cava; LEPAD, lower extremity peripheral arterial disease; PCI, percutaneous coronary intervention; revasc, revascularization.
Physician fee schedule, the worst may be in the past. Moreover, the uncertainty about future payment updates for all physicians is giving way to greater optimism that Washington will finally address the shortcomings of the SGR as the key determinant of physician payment updates. The Congressional Budget Office has lowered the estimated 10-year cost of holding the fee schedule constant from $244 billion to $138 billion thanks to a decline in actual Medicare spending growth compared to historical trends. The new estimate offers a window of opportunity to permanently dismantle the SGR within the year.

**RISE OF ACCOUNTABLE PAYMENT MODELS**

Even as resolution on physician payment appears within reach, broader health care reform efforts promise more disruptive changes to hospital and physician payments. Specifically, payers are seeking to shift greater risk to providers for the overall cost and quality of care. For Medicare and some commercial payers, the mechanisms being deployed include value-based purchasing (VBP), readmission penalties, bundled payment, and shared savings initiatives (Figure 7). In the VBP program, CMS evaluates hospitals based on achievement and improvement on selected clinical and patient experience measures. All hospital payment is reduced by 1% in 2013, and then by an additional 0.25% each year through 2017. Based on their performance, hospitals may earn back these dollars and receive an annual incentive payment.

Unlike VBP, the readmissions reduction program is a penalty-only program and focuses on all-cause readmissions for heart failure, acute myocardial infarction, and pneumonia in 2013, with potential expansion to other conditions including vascular interventions in 2015. Higher-than-average readmissions rates will result in penalties that are capped at 1% initially but increase to 3% by 2015.

For physicians, CMS currently offers several payment incentives, including the Physician Quality Reporting System, the Electronic Prescribing Incentive Program, and the Electronic Health Records Incentive Program. These programs use a combination of incentive payments and payment adjustments to promote reporting of quality information, use of electronic prescribing, and demonstration of meaningful use of electronic health record technologies (Figure 8). In terms of true pay for performance, CMS has just begun to outline parameters for the Value-Based Payment Modifier, which will roll out between 2015 and 2017 and provide a positive or negative multiplier to payment rates based on quality and cost performance.
Bundled payment and shared savings are the more disruptive innovations underway. In February, CMS announced that more than 450 health care organizations will participate in its Bundled Payments for Care Improvement initiative, which reimburses providers for certain care episodes through single case rates and enables gainsharing among collaborating providers. The initiative is composed of several broadly defined models of care based on various permutations of provider types and episode duration. The program aims to reduce cost by requiring pricing discounts and by aligning the financial incentives of all participating providers. Endovascular providers may be especially interested in bundling given that cardiovascular conditions represent a large portion of the costliest episodes of care. Select cardiovascular bundles include both cardiac and peripheral vascular interventions. To achieve savings, programs may target areas of high spending variability including drug expenditure and physician preference items (e.g., catheters, balloons, and stents).

Shared savings programs and accountable care organizations (ACOs) both describe payment models in which providers receive fee-for-service payments and potential bonuses based on their ability to lower the total cost of care while meeting quality targets across an entire population. As of January, there were approximately 260 Medicare ACOs, most of which are physician-led. The degree of upside and downside financial risk, minimum number of beneficiaries required, and methodology for calculating cost benchmarks differ across Medicare and commercial ACO models. For CMS, an ACO must include primary care and serve at least 5,000 beneficiaries. However, unlike payment bundling, specialty care—including cardiovascular services—often is not directly involved in ACO strategy. A 2012 survey of cardiologists indicated that only 2% are participating in an ACO. This will likely change in coming years because while initial ACO savings have been attributed to lower prices from shifting procedures and testing to facilities with lower fees, over time ACOs will need to work with cardiovascular specialists to manage patients together to achieve further cost and quality gains.

As payment and care delivery transformation accelerates, providers will need to contend with diverging incentives (Table 3). In fee-for-service medicine, the market disproportionately rewards specialty (largely acute care-focused) services. Financial success is a function of procedure and patient visit volumes and controlling operating costs. The emerging era of total cost management places premium value on primary care, reduced health care utilization, and ongoing care management. To achieve these objectives, health care systems are developing increasingly exclusive provider networks rooted in quality and cost performance. Endovascular specialists must respond with a commitment to partnership on key initiatives, including efforts to standardize care, define referral standards, and improve coordination across specialists and sites of care. The risks of not being an active participant in care delivery transformation are significant, including steerage to other providers and exclusion from preferred payer contracts.

**SUMMARY**

Endovascular services have experienced a rapid, dynamic evolution, enabling multiple paradigm shifts in the treatment of vascular disease and beyond. The market has expanded significantly, and today’s practitioners from many disciplines see themselves as endovascular specialists. Technology advancements and favorable economics have played important roles in this transformation. However, the broader health care environment is evolving quickly as well and will influence the future prospects for endovascular services. In the shift toward provider accountability, endovascular services increasingly will be scrutinized relative to the overall value they provide as measured by clinical and financial metrics.

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**TABLE 3. ACTIVITIES REWARDED UNDER DIFFERENT MARKET SCENARIOS**

<table>
<thead>
<tr>
<th>Era of Fee-for-Service Medicine</th>
<th>Era of Total Cost Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growth of profitable procedures</td>
<td>Decreasing utilization/total cost</td>
</tr>
<tr>
<td>Investments in specialty care</td>
<td>Investments in primary care</td>
</tr>
<tr>
<td>Investments in acute care</td>
<td>Investments in care continuum</td>
</tr>
<tr>
<td>Reducing operating costs</td>
<td>Patient engagement/self-management</td>
</tr>
<tr>
<td>Addressing episode-specific quality, cost metrics</td>
<td>Addressing broad quality and utilization metrics</td>
</tr>
</tbody>
</table>

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38 ENDOVASCULAR TODAY MARCH 2013
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