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## Welcome.

From the teaching spaces of the School of Medicine to the clinic examining room to the hospital bedside, we are all part of Duke Medicine.

As a community of physicians, we are bound together by our common education and profession, as well as a common mission, which is summed up in three words — quality patient care.

Every community needs a way to communicate. Duke Medicine Consults will provide information on contemporary issues in medicine from the Duke perspective. In this edition, your Duke colleagues give their perspectives on two timely issues — PSA tests and treatment of Type 2 diabetes.

You, too, can contribute to this newsletter. I'd like to hear your ideas. Please send them to Ms. Cynthia Gordon, administrative director of medical affairs, at [cynthia.gordon@duke.edu](mailto:cynthia.gordon@duke.edu).

*Michael Cuffe, M.D.*



Michael Cuffe, M.D.  
Vice president for  
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## CLINICAL PERSPECTIVE

# Management of Type 2 Diabetes Mellitus

Mark Feinglos M.D., C.M.; Harry R. Phillips III, M.D.; Michael A. Blazing, M.D.;  
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One of every nine Americans over age 20 has Type 2 diabetes mellitus (T2DM), and up to 40% have prediabetes, defined as impaired fasting glucose and/or impaired glucose tolerance. The disease is the seventh leading cause of death among Americans, and persons with T2DM are twice as likely to die compared with age-matched persons without diabetes. They also have a 4-fold higher risk of developing cardiovascular, cerebrovascular, or peripheral vascular disease and higher rates of blindness, renal disease, peripheral neuropathies, dental disease, and complicated pregnancy.

## Screening and Diagnosis: a Community Perspective

The presentation of patients with diabetes has changed over time. It remains particularly prevalent in older and obese patients and those with a family history of diabetes, previous gestational diabetes, impaired glucose metabolism, or physical inactivity. It also remains more prevalent in minority U.S. populations.

However, the median age at diagnosis

has been decreasing for several years. In an anecdotal report from one state, children with T2DM now outnumber those with Type 1 DM. As in adults, the disease is particularly prevalent in minority children and adolescents.

Glucose status should be part of routine medical examinations. Using a fasting sample for diagnosis carries limitations, however. First, the current cutoff value for diagnosis of T2DM — fasting serum glucose level <126 mg/dL — might be too conservative, given the expanding diabetic [page 2 ➔](#)

population. Obtaining fasting samples can be inconvenient for patients, who often must make separate trips to the clinic for testing. Using a postprandial sample for screening, although more convenient, is less accurate and requires repeat confirmatory testing. Hemoglobin (Hgb) A1C level might be an alternative, but no standards exist for its diagnostic use.

## Current Issues in the Management of T2DM

### Glycemic Control

The first and most critical method for glycemic control is optimization of diet and exercise. The specific regimens to be followed will vary among individuals, but overall calorie control is imperative, as is achieving balanced intake of protein, carbohydrate, and fat. Among patients with early-stage T2DM who still secrete insulin, up to 25% can achieve good glycemic control through diet and exercise changes alone.

If glucose status does not improve with diet and exercise, medication should be considered. Oral treatment, whether monotherapy or combination treatment, must be individualized according to patient and disease characteristics. Metformin might be appropriate for use in overweight patients who are insulin-resistant but still secreting insulin, but not for patients with renal or heart failure. In patients with significant heart disease, oral choices are limited. Sulfonylureas such as glimeperide or glipizide might be considered, but they can cause hypoglycemia and weight gain.

Recent controversy over the thiazolidinedione agents (TZDs) highlights the need for individualized therapy. They can exacerbate congestive heart failure, and rosiglitazone has been linked with possible myocardial ischemia. The TZDs may protect b-cell function, but they also can cause significant weight gain and edema. In addition, their glycemic effects can take months to achieve. Thus, TZDs probably should be reserved for second-line therapy in

selected patients, given the prevalence of cardiovascular and renal disease in this population.

Adding a glucagon-like peptide (GLP-1) agonist might offer benefit to patients with an incomplete response to metformin, sulfonylureas, or both. One such agent has been approved in the U.S., exenatide. It is a synthetic GLP-1 incretin, a hormone produced by the gut after meals. GLP-1 increases pancreatic insulin secretion during periods of elevated blood glucose levels, slows glucose absorption from the gut, and reduces the release of glucagon. Exenatide, a twice-daily injection, exerts a longer effect than does human GLP-1 because it is inactivated more slowly by dipeptidyl peptidase IV (DPP-4), the protease responsible for inactivation of incretin hormones. An oral approach is offered by the DPP-4 inhibitors, of which one agent has been approved for monotherapy in the U.S., sitagliptin.

Another new drug class for diabetes treatment is the amylinomimetics. As with incretin mimetics, only one amylinomimetic is approved for use in the U.S. Pramlintide is a modified, longer-acting form of amylin, a hormone normally cosecreted with insulin. Amylin reduces the rate of digestion and suppresses an excess release of glucagon after meals. It is approved for use as an adjunct to insulin.

Insulin can be appropriate for both newly diagnosed patients with extreme hyperglycemia and patients for whom other therapies are either inappropriate or unsuccessful. Insulin use should not be portrayed as a “punishment” or “failure” for patients. It is perfectly reasonable to supply additional insulin for patients with secretory defects, for example. The insulin formulation used should be tailored to specific treatment objectives: overnight control, reduced glycemic response to meals, etc.

Bariatric surgery might represent a non-pharmacological treatment option. In a recent study at Duke, all 314 diabetic patients enrolled had reduced the dose or number of antidiabetic medications taken by 12 months. Of the 71 patients with the most severe disease, nearly half

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### MISSION:

To facilitate communication among Duke-affiliated physicians by providing the Duke perspective on contemporary issues in medicine.

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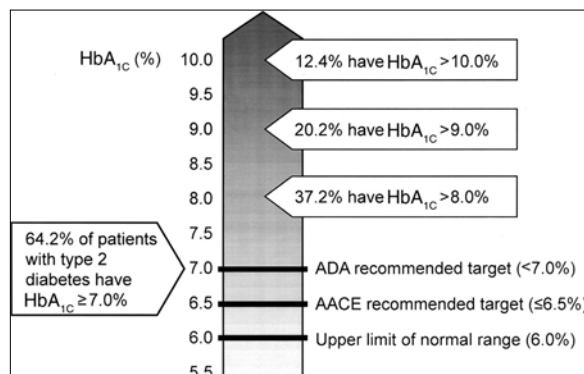


Figure 1

Recommended goals for glycosylated hemoglobin (HbA1c) remain unmet in the majority of patients with Type 2 diabetes mellitus. AACE = American Association of Clinical Endocrinologists; ADA = American Diabetes Association. (Adapted from American Journal of Medicine, JAMA and Diabetes Care.)

achieved outright remission of diabetes (cessation of antidiabetic medications and normal hemoglobin A1c levels). Lap-band surgery also has shown promising results. Improvements have been at least partly attributed to postoperative changes in hormone secretion by the gut and pancreas. With either procedure, however, patients must continue to follow diet and exercise recommendations to achieve long-term success.

### Reducing Cardiovascular Risk in Diabetic Patients

Diabetic patients have a high risk of cardiovascular disease and its complications. The risk of myocardial infarction (MI) in diabetic patients is identical to that of nondiabetic patients with previous MI, and the five-year death rate after MI is twice as high in diabetic versus nondiabetic patients. Because of this increased baseline risk, however, diabetic patients can derive relatively greater benefit from interventions such as bypass surgery and medication.

Control of hypertension to <130/80 mm Hg can halve the risk of MI or stroke in diabetics and reduce the risk of selected microvascular complications by ~33%. The risk of cardiovascular complications also can be halved through better control of very low-density lipoprotein cholesterol (VLDL) and LDL, which together are a surrogate measure of apolipoprotein B, the major apolipoprotein of all atherogenic lipoproteins.

Aspirin prophylaxis also should be used to reduce cardiovascular risk, unless contraindications exist. Providers should encourage patients to follow diet and exercise recommendations, stop smoking, and take medications as directed. Involvement of the patient's support network can also be very effective.

### Preventive Care


Diabetic patients should receive regular eye and foot examinations. Good blood pressure control can substantially ameliorate declines in renal function. Angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) are the preferred treatment options for this indication. Both types of agents also reduce proteinuria, a risk factor for renal impairment.

## Future Directions

Clinical research continues to elucidate the most effective interventions for diabetic patients. One Duke study is assessing the effects on glycemic control of eliminating one item from the diet, such as sweetened drinks. The potential advantage of such a simple intervention is that it would be less overwhelming to patients compared with wholesale lifestyle changes, and it would therefore carry a greater likelihood of compliance. Other research is assessing the effects of caffeine on glycemic control— caffeine can increase postprandial glucose levels by 20%. Follow-up also continues on the ACCORD study of diabetic patients with especially high risk of cardiovascular disease, which recently reported increased mortality with very intensive glycemic control versus standard therapy. The patients in the intensive-therapy arm have now crossed over to standard therapy, and their outcomes are being assessed.

The level of Hgb A1c that should be used to guide pharmacological glycemic control has been controversial of late. The American Diabetes Association recommends an Hgb A1C goal for nonpregnant adults of <7%, reflecting the improved outcomes at this level seen in clinical trials. This is in agreement with the recently released data from the ACCORD study. However, selected patients, especially younger individuals with newly diagnosed diabetes, may derive benefit from reducing the Hgb A1c level to as close to normal (<6%) as possible, assuming they do not develop significant hypoglycemia.

## Summary

Type 2 diabetes mellitus represents a growing and serious public health issue in the United States. Aggressive screening and management of the disease are required to avoid complications; clinicians should therefore incorporate measurement of glucose status into routine patient care. With lifestyle changes, careful glycemic control, and regular preventive care, patients with diabetes can minimize their risk of complications and improve their quality of life. 



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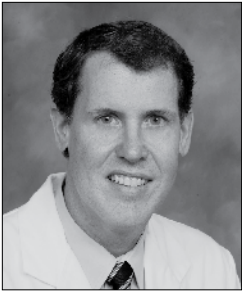
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# The State of Prostate Cancer Management

## A View from the Duke Prostate Center

Judd W. Moul, M.D., FACS

More than 189,000 American men will be diagnosed with prostate cancer in 2008, and 29,002 men will die from it. In fact, prostate cancer is the third leading cause of cancer-related death in American men. The disease is most prevalent in black men, and >60% of all prostate cancers are found in men aged 65 years or older.

Although the incidence of prostate cancer has remained steady overall since 1995, corresponding death rates have decreased substantially—from 3.5% yearly for Hispanic men to 6.0% yearly for black American men. These improvements in survival reflect advances in early detection, medical therapies, radiation therapy, and surgery.

### Screening, Early Detection, and Risk Assessment

In addition to digital rectal examination, the cornerstone of prostate cancer screening remains the prostate-specific antigen (PSA) test. The regular use of these screening methods facilitates early detection of prostate cancer; however, the use of the PSA test carries important limitations.

Elevated PSA levels do not necessarily indicate the presence of cancer; they can also occur with conditions such as benign prostatic hyperplasia and prostatitis. The sensitivity and specificity of PSA results also can vary by age, race, and assay method, resulting in possible false-negative and -positive results. Finally, even if cancer is discovered via the test, results cannot always be used to guide treatment. Some prostate cancers, particularly among elderly men, grow so slowly that the patient's health may never be affected. Whether a given tumor falls into this category cannot necessarily be determined from PSA results.

No scientific consensus exists about the optimal use of PSA screening. However, white men without symptoms or family history of prostate cancer generally should begin annual testing at age 50, whereas black men and those with a family history should begin testing at age 40. Conversely, screening may be unnecessary for men aged  $\geq 75$  years, although this is controversial.

According to recently issued guidelines from the National Comprehensive Cancer Network and American Urological Association, all men should have a baseline PSA level measured at age 40. If low (typically  $\leq 0.7$  ng/mL), another test is not needed until age 45. At 45, another PSA test should be performed and the same rule applied. If the PSA at age 40 is  $>0.7$  ng/mL, however, men should be watched more closely,

undergo annual testing, and, if the PSA reaches  $>2.5$  ng/mL, undergo biopsy. This is an outpatient, transrectal ultrasound-guided needle biopsy performed under local anesthesia. Only a biopsy can determine conclusively the presence of prostate cancer.

### Treatment Options

If a simple "active surveillance" strategy is inappropriate, many options are available for patient management. These can be split into three broad specialties: medicine (urology, genitourinary medical oncology), radiation oncology, and urological surgery. Evidence-based programs for disease management, such as at the Duke Prostate Center (DPC), use a multidisciplinary approach encompassing all three specialties. Such an approach facilitates coordination of care, research efforts, and patient convenience and involvement in treatment.

#### Medical Management

Several drug classes are used in prostate cancer management. Patients with locally advanced tumors might benefit from surgical or pharmacological castration, which deprives the tumor of androgen. Drugs used in this approach include luteinizing hormone-releasing hormone (LHRH) agonists such as leuprolide and goserelin. Treatment results in loss of libido, erectile dysfunction, possible hot flashes, and metabolic effects such as osteoporosis.

Some patients may benefit from the addition of direct antiandrogen agents to LHRH agonism, tailored to the individual patient. Long-term androgen deprivation can cause osteoporosis, anemia, and loss of muscle mass. Exogenous estrogens are used only rarely because of the increased risk of thromboembolic complications. There is no standard hormonal therapy for castration-refractory prostate cancer (CRPC).



Chemotherapy, with or without hormone therapy, can be used to manage high-grade tumors extending beyond the prostatic capsule. Such therapy is typically used before surgery or in conjunction with radiation. For patients with metastatic CRPC, the use of estramustine, docetaxel, or mitoxantrone with prednisone improves quality of life and prolongs the time to cancer progression. Docetaxel is the only chemotherapy shown to extend survival in CRPC.

### Radiation Oncology

The standard of care for external radiation therapy for prostate cancer is conformal three-dimensional radiation therapy and intensity-modulated radiation therapy, which can safely deliver doses approaching 80 Gy to the prostate. Adverse effects can include erectile dysfunction, radiation proctitis, cystitis, diarrhea, fatigue, and urethral strictures, particularly if patients have undergone transurethral resection of the prostate. Outcomes of radiation therapy can be comparable to those after prostatectomy, particularly among patients with low-risk features.

Brachytherapy is a minimally invasive alternative to surgery or external-beam radiation for patients with early-stage disease. Radioactive seeds or pellets are implanted into the prostate, resulting in local tissue necrosis. Ultrasound imaging is used to guide pellet placement, so that ablation is achieved with minimal radiation exposure for adjacent tissues.

### Surgical Options

Because prostate cancer typically manifests as multiple distinct tumors located throughout the prostate, most surgical approaches target removal of the entire gland. Radical retropubic or perineal prostatectomy was the standard method for years. Its major limitations include postoperative erectile dysfunction and possible urinary incontinence. Recent years have seen development of nerve-sparing radical prostatectomy (NSRP), which removes the prostate while preserving the adjacent nerves that control urinary and erectile function. Refinements in NSRP have minimized transfusion use, surgical incision length, and operative/anesthesia times. Men undergoing NSRP are likely to fully regain preoperative sexual and urinary function.

Robotic radical prostatectomy (RALP) has been offered at Duke since 2003. In RALP, surgeons operate with a four-arm robotic system that allows fine manipulation through tiny incisions. The best candidates for RALP are normal-weight patients who have small, early-stage cancers.

Whether RALP truly offers any significant advantages over NSRP is being hotly debated by urological surgeons. Proponents of RALP contend that the visual ability to operate is enhanced, and postoperative recovery is better.

Those favoring NSRP believe that tactile ability allows experienced surgeons to do a better job. The DPC is conducting outcomes research to address this issue. Patients undergoing these procedures at Duke are asked to complete questionnaires about their urinary and sexual function before and during the first year after surgery, to allow comparisons of RALP with NSRP.

Cryotherapy ablation is a minimally invasive option for patients who are not candidates for surgery/radiation and for those who elect this approach. Guided by ultrasound imaging, surgeons insert fine needles into the prostate and freeze them with cooled gases. The cooling produces ice bulbs around the needles, causing necrosis of adjacent tissue. Impotence is likely after this procedure. Duke researchers are now testing “focal” cryotherapy in men who have small tumors, in which only part of the prostate is frozen so as to maintain sexual function and lessen other side effects.


## Emerging Approaches

Studies of finasteride treatment for benign prostatic hyperplasia have recently shown additional value in the prevention of prostate cancer. Furthermore, in a recent trial, finasteride combined with flutamide, an oral antiandrogen, suppressed long-term PSA levels in men with elevated PSA levels after radical prostatectomy. DPC researchers are continuing to study this so-called “peripheral androgen blockade” approach.

New anticancer drugs include inhibitors of the mammalian target of rapamycin (mTOR) protein, which stimulates growth of prostate cancer cells. Vaccines are also in Phase 3 trials in patients with metastatic CRPC. Another Duke trial in men with high-risk, localized disease is combining pre-surgery external-beam radiotherapy with radical prostatectomy.

Lifestyle changes are also under investigation. A large trial is assessing the effects of ground flaxseed on testosterone and PSA levels. Other studies are examining the effects of diet and exercise on markers of cancer progression and quality of life, and how obesity might promote prostate cancer and alter early-detection efforts.

## Summary

Advances in early screening and the development of multidisciplinary disease-management programs have greatly reduced mortality from prostate cancer. Further refinements in PSA and other diagnostic testing can only improve the early identification of the disease. In the meantime, screening should be incorporated into routine examinations as recommended by recent practice guidelines. 



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## Election presents uncertainties, but support for NIH funding shows hopeful sign

Paul A. Vick and Kevin A. Schulman, M.D.

Despite talk of sweeping health care reform from this year's presidential candidates, significant change isn't guaranteed. Indeed, the extent to which change may occur depends on several potential scenarios. If elected, Republican U.S. Sen. John McCain of Arizona likely would offer restrained proposals reflecting his party's preferences for indirect approaches such as tax credits and market incentives. U.S. Sen. Barack Obama, a Democrat from Illinois, likely would propose comprehensive, immediate changes via new mandates on individuals and employers, new programs and increased federal spending. The highest potential for significant change would emerge with both a Democratic president and Congress.

### Federal funding

#### For research

A major issue for physician-researchers is research funding from the National Institutes of Health.

Whatever November's outcome, analysts believe relief for the NIH funding crisis may materialize. Encouraging but far from definitive signs include the extra \$150 million for NIH added to the 2008 fiscal year supplemental spending bill Congress passed in June, and the additional \$500 million proposed by the Senate Appropriations Committee in the second FY 2008 emergency spending bill, now under consideration. Also, U.S. Sen. Tom Harkin, D-Iowa, and U.S. Sen. Arlen Specter, R-Pa., introduced legislation to increase FY 2008 supplemental NIH funding by \$5.2 billion to help restore the agency's research capacity.

#### For reimbursement

Uncertainty deepens after the 2008 election. While health care dominated the early phase of the campaign, it faded as other issues, such as the economy, gained momentum. Washington insiders generally don't expect substantive activity on the health care front until after the 2010 congressional elections.

Though no serious discussion is occurring now, the Medicare reimbursement dilemma remains the top policy issue for physicians. While the current payment formula is widely viewed as critically flawed, Congress continues to favor small, last-minute fixes over far-reaching revisions.

The struggle is illustrated by Congress' mid-July vote to override President Bush's veto of H.R. 6331, a bill that retroactively prevented a 10.6 percent cut in physician reimbursements. Unless Congress acts in the next two years, physicians will face another major Medicare

payment cut in 2010. With increasing domestic and foreign demands on the federal budget, Congress will be harder pressed to find money to cover the widening gap.

### Wild card issues


In a McCain or Obama presidency, analysts see several potential wild card issues, including:

Will reimbursement based on performance and outcomes reward high-performing providers? As an early adopter and leader in patient safety and quality-of-care measures, Duke Medicine would fare well in this scenario.

Will a decrease in uncompensated care require hospitals to redirect community benefit efforts, particularly important for nonprofits? National and state lawmakers are asking cogent questions about what the public should expect in return for hospitals' tax-exempt status. While DUHS is reasonably well-positioned with many effective community programs, it would need to increase its future commitment to Durham and surrounding communities should this occur.

Will, for employers, the potential for individuals to opt out of employer-sponsored insurance plans change recruitment and retention practices? With Duke being one of the state's largest private employers, employee-benefit policies, including health insurance, are vital considerations.

### Summary

In the end, amid uncertainties as the election plays out, current efforts to increase NIH funding stand as a hopeful sign. With the expanding deficit and softening economy, however, hard choices loom about Medicare reimbursements and other issues as the public's priorities encounter what the new president and reconstituted Congress can deliver. 

## Quality Measures: Important today, absolutely critical tomorrow

Larry Moss, M.D.

It comes as no surprise to learn that there is an ongoing financial crisis in American health care. Change in health care has often been about the dollar, but that change is now focused on one thing – quality. That quality is being recorded and measured like never before.

The federal Centers for Medicare & Medicaid Services (CMS) measures and reports a variety of outcomes. A new program, Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS, or ‘H-caps’) surveys patients on a variety of metrics that range from whether their room was quiet and clean, to how well doctors and nurses explained treatments and medications. Beyond mere measurement, these data are now made available over the Internet for use by patients in making decisions about where they go for their care. Duke scores above the national and state averages in almost all of these metrics. There are also those where we fall short and require improvement.

To this point, these measurements have focused on hospital care, and they haven’t been much more than a novelty. But, we are witnessing just the early days of a quality measurement system that will have lasting impact. This measurement and scrutiny will only become more intense and its relevance will only increase for physicians, whether one practices in a hospital, clinic or private practice.

My view is that we should all welcome this scrutiny. Quality issues are important for two reasons. First, because, quality is about doing the right thing — the right care for the right patient at the right time. And second, because they are inextricably linked to the future of our enterprise, our profession, and in the very near future our own individual practices and reputation.

While the public hasn’t grabbed onto these data thus far, there is finally a little more attention being given to this topic. Just in the last couple of weeks, *USA Today* published a front page story on CMS quality measures for heart attack, heart failure and pneumonia. Private information providers, such as Angieslist.com,

are rating individual physicians. The American Medical Society, other physician groups and insurers have agreed to the Patient Charter for Physician Performance Measurement, Reporting and Tiering Program, standards that will allow for reporting of individual physician performance.


Increasingly, payors will reimburse for quality care. They will not pay for care that is determined to be sub-standard by objective measurement data. Also, the view over the horizon is that quality performance, linked to 2 percent of reimbursement today, could possibly be linked to 10 percent to 15 percent of reimbursement in the future.

At Duke, we have embedded systems to gather the metrics, ascertain scientifically-valid treatment protocols and to prove to private and public payors, our patients and ourselves that we performing at a high level and are working to continually improve that performance.

What’s next?

It’s about getting into the nitty-gritty of our processes. Take one example: Not every patient gets that aspirin when they present with chest pains. We’ve installed computerized physician order entry (CPOE) at Duke Hospital and Durham Regional to address that. This is not medicine by recipe but a beneficial “best practice” safety net for physicians. The intent of this automation is not to replace the physician’s clinical judgment. The patient’s best interest is — as always — the primary focus. However, as the complexity of medicine outdistances the limits of human performance, we will more and more rely on automated procedures that ensure patients are treated in standard ways.

In the clinics and practices, physicians should be demanding of administrators the tools they need to manage across their patient populations. Not every one of the 1,000 patients in a primary provider’s panel who should get an influenza vaccination gets one. I respectfully suggest we must establish systems that do that.

When we focus on quality, patients win, and so do we. 



Larry Moss, M.D.  
Chief medical officer,  
Durham Regional Hospital



## CME CALENDAR

*Selected continuing medical education opportunities*

### **Oct. 2–4**

Anesthesia Camp V  
Montage Resort & Spa, Laguna Beach, Calif.  
[info@destinationcme.com](mailto:info@destinationcme.com)

### **Oct. 18–21**

Musculoskeletal MRI and Neuroimaging:  
An Update  
Grove Park Inn Resort and Spa, Asheville  
[radiology.duke.edu](http://radiology.duke.edu)  
(336) 499-6705

### **Oct. 25**

9th Annual Hampton Roads Oncology  
Educational Conference  
Hilton Virginia Beach, Virginia Beach, Va.  
(919) 419-5506

### **Oct. 29–Nov. 1**

Anesthesia Camp: Lana'i 2008  
Four Seasons Resort, Lana'i, Hawaii  
Inquire: [info@destinationcme.com](mailto:info@destinationcme.com)

### **Nov. 1–2**

The 35th Annual Postgraduate Course  
The Alexander Spock Symposium:  
Pediatric Urgent Care  
Searle Center,  
Duke University Medical Center  
(919) 684-2289 or [cates004@mc.duke.edu](mailto:cates004@mc.duke.edu)

### **Nov. 4**

Duke Tuesday in Urology  
Searle Center,  
Duke University Medical Center  
(919) 684-4314

### **Nov. 8–11**

Update on Cardiopulmonary  
and Abdominal Imaging  
Disney Yacht & Beach Club, Orlando, Fla.  
[radiology.duke.edu](http://radiology.duke.edu)  
(919) 684-7228

### **Dec. 12**

DUHS 4th Annual Patient Safety Conference  
Marriott Hotel, Durham  
(919) 668-6068

### **Dec. 12–13**

From Foam to Filters:  
What's New in Venous Disease 2008  
Washington Duke Inn & Golf Club, Durham  
(919) 401-1204

### **Jan. 28–31, 2009**

Anesthesia Camp II  
The Ritz Carlton, St. Thomas,  
U.S. Virgin Islands  
[www.destinationCME.com](http://www.destinationCME.com)



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