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# Lourdes

## HealthViews

### **A2** Personalized Breast Cancer Therapy Replacing One-Size-Fits-All Approach



Research has intensified toward personalized breast cancer treatment, shifting away from a one-size-fits-all approach to more tailored therapies based on the tumor's genetic composition. Discovering a tumor's genetic signature allows Lourdes cancer specialists to more effectively determine prognosis and treatment for the patient.

### **A4** Three Confounding Issues for Clinicians Who Treat Athletes: Diabetes, Asthma and Supplements



Lourdes Health System presents summaries from its second annual New Frontiers in Sports Medicine, which attracted more than 150 physicians, physical therapists, nurses, sports trainers and staff to a day-long CME event.

### **A6** Biventricular Pacing Prevents Hospitalization, Extends Lives, in Advanced CHF Patients

Patients diagnosed with serious or severe congestive heart failure typically survive for only a matter of months. Usually, they experience expensive and repeated hospitalizations and poor quality of life. Cardiac resynchronization therapy, available at Our Lady of Lourdes Medical Center, reduces the risk of death or hospitalization compared to medical treatment alone.

### **A7** Lourdes News

Our Lady of Lourdes Medical Center participates in Medicare gainsharing project; American Heart Association/American Stroke Association honor Lourdes Stroke Program.

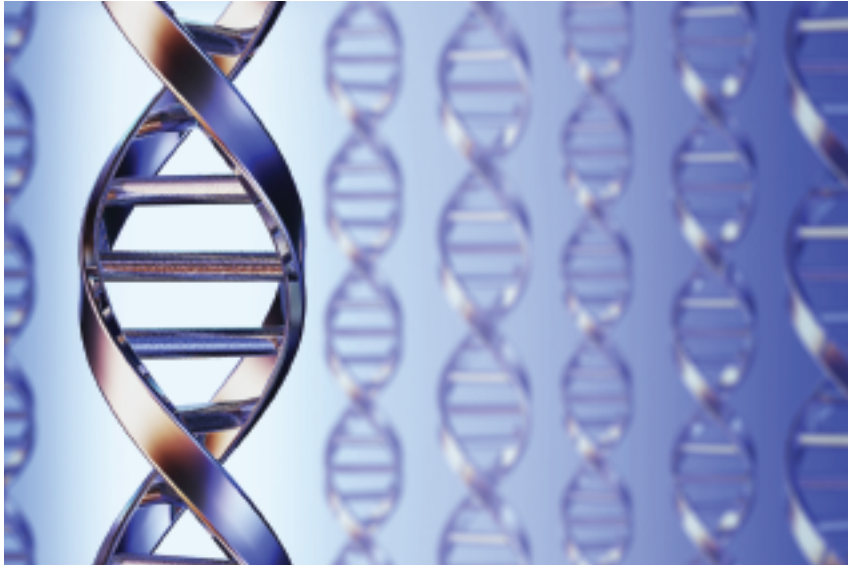
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# Personalized Breast Cancer Therapy Replacing One-Size-Fits-All Approach



*Research has shifted away from a one-size-fits-all approach to more tailored therapies based on a tumor's genetic composition. Discovering the cancer's genetic signature allows physicians to more effectively determine prognosis and treatment.*

Research has intensified toward personalized breast cancer treatment, shifting away from a one-size-fits-all approach to more tailored therapies based on the tumor's genetic composition.

Discovering the cancer's genetic signature allows physicians to more effectively determine prognosis and treatment for the patient, said **Arnold Baskies, MD**, chief of the sections of general, oncologic and breast surgery at Lourdes Medical Center of Burlington County.

"The greatest advance in the care of the patient with breast cancer is attributable to the decoding of the human genome. This has already produced incredible benefits for our patients, and will result in the development of truly personalized health care for each patient, as we fully identify the molecular pathways and inhibit enzymes and genes that are the basis for cancer," said Dr. Baskies, president-elect of the American Cancer Society,

Eastern Division, and chairman of the Governor's Task Force on Cancer Prevention, Early Detection and Treatment. "Indeed, instead of taking a shotgun approach to try to kill cancer cells, this allows our therapeutic options to be more like an assassin's bullet."

## **Deciphering the Signature**

A cancer's genetic signature is the determinant of its stage (size, invasive or noninvasive, lymph node involvement and localized vs. metastatic); grade; estrogen and progesterone receptor status; and HER2 receptor status.

Depending on the tumor type, gene assay tests are available to help predict the most effective adjuvant therapy. For example, the OncotypeDX™ (Genomic Health, Inc.) test examines the RNA of 21 genes in patients who have estrogen-receptor positive, lymph node-negative breast cancers and is now being extended to some node-positive cases. This assay generates a recurrence score, which estimates the patient's risk of 10-year distant

recurrence, as well as whether she will benefit from chemotherapy. Approximately half of women tested are found to be at low risk and are provided endocrine therapy alone, either with tamoxifen (Nolvadex®) or an aromatase inhibitor, said **Priya P. Gor, MD, MSCE**, a medical oncologist on staff at Our Lady of Lourdes Medical Center. Women at high risk are given chemotherapy in addition to adjuvant endocrine therapy.

Another assay, MammaPrint (Agendia), utilizes a microarray analysis of 70 genes from fresh tissue to determine if a patient is at low or high risk of the cancer metastasizing. The test is generally used to assess recurrence risk in patients who are under age 61 and have stage I or II breast cancer, negative nodes and a tumor 5 centimeters or less in size.

"These assays allow us to bridge the gap between basic cancer biology and personalized clinical care," Dr. Gor said.

## **Treatment Options**

Based on the tumor's specific characteristics or genetic signature, physicians can decide on a treatment or combination of treatments that offer the best chance for success. Those treatments include surgery, chemotherapy, radiation, targeted therapy and hormonal (endocrine) therapy.

"Every cancer has its own genetic signature which determines prognosis

and treatment,” Dr. Baskies said. “We, therefore, don’t have to treat every single patient with chemotherapy.”

Earlier this year, the 2009 St. Gallen International Expert Consensus issued new general guidelines for treating early-stage breast cancer.<sup>1</sup> The panel called for all clinical decisions in systemic adjuvant therapy to be based on a new treatment algorithm. The guidelines include:

- Adjuvant endocrine therapy is recommended for most patients with any detectable level of estrogen receptor (ER). Endocrine therapies include tamoxifen and aromatase inhibitors.
- Targeted anti-HER2 therapy, such as trastuzumab (Herceptin<sup>®</sup>) is recommended for almost all patients with HER2-positive disease.
- Chemotherapy, which can reduce the risk of early-stage breast cancer recurrence, should be the mainstay of treatment for patients with triple negative or HER-2 positive breast cancers. Less consensus exists about its effectiveness with ER-positive, HER-2 negative disease associated with negative lymph nodes in post-menopausal women.

### Next Steps

“Due to advances in the treatment of early-stage and metastatic breast



cancer, not only are we treating patients with less chemotherapy, but we are also offering smarter therapies that target biological pathways of cancer growth,” said Dr. Gor. A number of biological agents are currently being used, including for example, Herceptin and lapatinib (Tykerb<sup>®</sup>), which inhibit the HER-2 pathway. In addition, trials are underway that are linking chemotherapy to targeted antibodies, such as TDM1 (trastuzumab-DM1), selectively delivering the drug into cancer cells.

Another focus is the vascular endothelial growth factor, or VEGF, protein. One drug, Avastin<sup>®</sup> (bevacizumab), inhibits the tumor’s growth through

preventing the development of new blood vessels which it needs for its blood supply. While the drug has shown benefit for metastatic disease when combined with chemotherapy, trials are studying whether it could be used in early-stage breast cancer, Dr. Gor said.

“Advances in the treatment of breast cancer are possible because of the combined efforts of laboratory scientists who discover and target biological pathways of growth, the clinicians who offer these discoveries to patients, and most importantly, to the patients who participate in clinical trials and enable us to learn whether these therapies are effective,” Dr. Gor said. “Because of this combined effort, we are now able to incorporate gene signatures into decision-making for chemotherapy, effectively offering less chemotherapy, and to offer smarter, targeted therapies.”

### Contact

To contact a Lourdes cancer specialist, call 1-888-LOURDES (568-7337).

## Breaking Lourdes Cancer News

On September 30, Our Lady of Lourdes Medical Center hosted a CME event, “Emerging Concepts in Breast Cancer.” Using i>clicker<sup>®</sup> technology, the multidisciplinary panel of Lourdes experts presented case studies and elicited physician responses to questions regarding management of breast cancer patients, including the appropriate use of genetic counseling.

To receive the latest National Comprehensive Cancer Network clinical breast cancer treatment guidelines, contact Theresa Campanella at 856-382-1804 or [campanellat@lourdesnet.org](mailto:campanellat@lourdesnet.org).

The Lourdes Health System, a leading center for robot-assisted and minimally invasive prostatectomy, is forming the Man-to-Man prostate cancer support group. If you have patients who may be interested in joining this new group, please have them call 1-888-LOURDES (568-7337).

<sup>1</sup> Goldhirsch A, Ingle JN, Gelber RD, Coates AS, Thurlimann B, Senn H-J, et al. Thresholds for therapies: highlights of the St. Gallen International Expert Consensus on the Primary Therapy of Early Breast Cancer 2009. *Annals of Oncology*. 2009;20(8):1319-1329. <http://annonc.oxfordjournals.org/cgi/content/full/mdp322>. Accessed September 10, 2009.



# Three Confounding Issues for Clinicians Who Treat Athletes: *Diabetes, Asthma & Supplements*

**Editor's Note:** This is the first in a series of articles summarizing presentations from Lourdes Health System's second annual New Frontiers in Sports Medicine conference held May 8, 2009 in Cherry Hill.

Presenting on **diabetes and the athlete**, Lourdes endocrinologist **Jenine Vecchio, MD**, noted that diabetes in no way precludes athletics. Yet across the population many with diabetes don't exercise, despite the physical and psychological benefits and the potential to improve the glucose cycle. Many are interested in exercising, however.

Should physicians screen diabetics for cardiovascular disease before recommending an exercise program? Dr. Vecchio said that clinicians must use their judgment, based on a detailed history and careful physical. They should be cautious with patients whose fasting sugar is very high or who have uncontrolled hypertension. Due to concern about neuropathy, they also should think about nonweight-bearing exercises, such as swimming or biking. Walking also can serve as a good start for some patients.

Exercise will influence the glucose cycle. "Every diabetic is different in how exercise affects the sugar cycle, and how they need to adjust the insulin regimen to account for effects of exercise," said Dr. Vecchio. "It can vary significantly across individuals and even from day to day."

Dr. Vecchio's recommendations for managing exercise in diabetics include:

- Bring type I diabetes under control before embarking on an exercise program.
- Avoid exercising when insulin action is peaking because blood glucose

could drop significantly. Similarly, patients may want to consider a lower dosage of insulin at mealtime, if they know they will exercise within a few hours (and thus need higher glucose levels).

- Patients on glucose pumps may want to adjust insulin rates around exercise.
- Diabetics should drink fluids to control gastroparesis and should have glucose tablets handy.
- After exercise, diabetics may want to eat dried fruits or other carbohydrate sources to maintain glucose levels.

Dr. Vecchio noted that, with exercise moderating insulin needs, diabetics have the potential to appreciate improved pancreatic function.

Presenting on **asthma and the athlete**, **Craig Kimmel, MD**, director of Primary Care Sports Medicine for the Lourdes Health System, said that asthma remains one of the most poorly treated conditions, and that exercise-

induced asthma is especially under-addressed. As a result, patients (especially young people) die on playing fields and at the hospital.

For the vast majority of asthmatics, exercise can induce an attack. Most patients who believe that they experience asthma induced by exercise only are suffering from asthma in a broader sense. Similarly, many patients who have breathing-related allergy symptoms have asthma as well. Thus, clinicians must treat the overall asthma condition.

To demonstrate adequate control, patients should not exhibit wheezing during or after exercise. Some may adjust by choosing a different sport, but most may participate in any sport as long as they have an inhaler. Patients, however, often comply poorly with inhalers, a problem frequently related to lack of knowledge about use of these devices. For example, patients may not know or remember to rinse out their mouths after an inhalation, in order to avoid the jittery side effects from oral absorption.





*“The best supplement you can take is healthy food that comes with as full a complement of natural nutrients as possible and is balanced nutritionally for your performance needs.”*

Ronald Ciccone, MD

“Just as critical, if you know an asthmatic who doesn’t have a peak flow meter, then you know someone whose asthma is uncontrolled,” explained Dr. Kimmel, estimating that 95 percent of asthmatics don’t have one of these compact, inexpensive devices that can help them determine the severity of an episode, decide when to use rescue medication and determine whether to seek emergency care.

Dr. Kimmel also advised that as soon as an asthmatic has exercise-induced symptoms, he or she should use the inhaler, as side effects of use are minor compared to an emergency situation. If they need repeat administration during activity, they should stop the activity. An epinephrine pen proves likewise essential for sports. Again, when in doubt, asthmatics should use the epi pen, as side effects or dangers of its use are not significant compared to a severe attack.

Dr. Kimmel cited a newer treatment, monthly immunoglobulin E (IgE) shots, as successful in helping some patients avoid other asthma medications. He also mentioned effective natural-herb therapy for patients who cannot tolerate prescription medications. Finally, stress—including the stress of competing—plays a role, and

learning deep-breathing and relaxation techniques can help athletes avoid this effect.

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 Discussing **supplements and the athlete, Ronald Ciccone, MD**, director of Integrative Family Medicine at Lourdes, noted that athletes express great interest in sports ergogenics in the form of performance-enhancing agents. The supplements are often banned, illegal or dangerous, but athletes may still gain the effects of the agents by taking their precursors.

“The best supplement you can take is healthy food that comes with as full a complement of natural nutrients as possible and is balanced nutritionally for your performance needs,” said Dr. Ciccone.

He noted that athletes in sports primarily requiring short, intermittent bursts of muscular strength should seek relatively more calories from protein—a better recovery and regeneration fuel, but one that brings greater amounts of nitrogen that can contribute to lactic acidosis. Athletes in sports requiring more constant motion and endurance will seek a

greater portion of calories from carbohydrates—a fuel, though, inherently associated with rising and falling blood glucose.

Among currently available products, Ultrafuel and Pro-Optimizer are popular in part for a balance of carbohydrates and protein, he said. He also pointed to Guna Son, taken for its amino-acid content and presumably lower nitrogen breakdown. He indicated that some athletes take ubiquinol, a pre-converted form of CoQ10, for its purported ability to combat fatigue (via stimulation of the electron-transport chain in mitochondria). He also cited Omeo-sport, with active ingredients in extremely low, homeopathic concentrations, aimed at metabolic stimulation of muscle fiber cells. Dr. Ciccone noted he does not recommend creatine.

Dr. Ciccone maintained that supplements derived from whole foods have greater bioavailability. He also suggested minerals and trace elements should have more consideration as performance supplements but that some cautions are necessary with this type of supplementation.

## Effect of Exercise in Poorly Controlled Diabetics

- Body depletes available muscle and blood glucose levels earlier
- Increased glucose production by the liver
- Increased utilization of fat from adipose cells
- Body turns to fatty acids as alternative fuel
- Metabolism of FFA results in ketones



# Biventricular Pacing Prevents Hospitalization, Extends Lives, in Advanced CHF

Patients diagnosed with serious or severe congestive heart failure (CHF) typically survive for only a matter of months. Usually, they experience expensive and repeated hospitalizations and poor quality of life. But a newer cardiac-pacing treatment improves this scenario for such patients who have significant arrhythmia.

According to data from the Cardiac Resynchronization—Heart Failure (CARE-HF) study,<sup>1</sup> cardiac resynchronization therapy (CRT) with atrial-synchronous biventricular pacing reduced the risk of death or hospitalization in this patient group by 37 percent, compared to medical treatment alone. Patients studied had advanced CHF (New York Heart Association Class III or IV), a reduced ejection fraction and a prolonged QRS duration on EKG, despite optimal medical management. Only about one-third treated with medication alone survived to three years; whereas, nearly three-fifths of those treated with CRT survived beyond three years.

“We also see amazing functional benefits. Patients who couldn’t walk to the bathroom can often get out of the house and walk completely around the block. It normalizes life for many patients,” said electrophysiologist **Darius P. Sholevar, MD**, who has helped to lead Our Lady of Lourdes Medical Center in implanting the new pacing systems.

## EF Improves

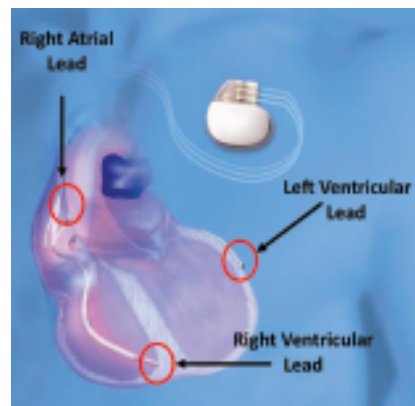
The procedure for implanting a biventricular pacemaker, also known as a cardiac resynchronization device, is similar to a pacemaker implant from a

patient’s perspective. After the patient is under conscious sedation, the electrophysiologist establishes intravenous access at the top of the chest via the cephalic or subclavian vein. The team then advances pacemaker wires through this sheath and into the heart, and places them in the right heart chambers. The wires connect to a pacemaker or defibrillator device implanted under the skin in the chest through a small incision.

The portion of the operation to this point exactly resembles a routine pacemaker implant. Proceeding further though, the electrophysiology team uses a spectrum of advanced guiding tools and sheaths to place an extra wire into a vein branch of the coronary sinus that runs on the epicardial surface of the lateral left ventricle. Hospital recovery time is typically 24 hours or less.

The resulting synchronized pacing of both sides of the main pumping chamber restores the coordinated contraction that many patients with advanced heart failure have lost. The heart’s ejection fraction (EF)—the most commonly used measure of heart muscle strength—improves, as the heart actually consumes less oxygen.

“The heart pumps more blood and works better while using less energy,” explained Dr. Sholevar, who has placed CRT implants since the U.S. Food and Drug Administration approved the systems in 2004. “Our ability to implant and optimize these devices has improved vastly in the last few years, with better catheters, guide wires and sheaths, and more sophisticated leads and pacing devices.”



*CRT has become a new standard for restoring function in patients with advanced CHF and cardiac dyssynchrony. The EP team places three leads, two in the ventricles and one in the right atrium.*

## Setting New Standard

The procedure produces enough improvement to prevent some end-stage heart failure patients from needing a heart transplant. Only a small handful of heart hospitals in southern New Jersey, with full cardiothoracic-surgery back-up, can now offer the procedure.

Biventricular pacing has become an accepted and critical part of managing congestive heart failure. Dr. Sholevar indicated that the success rate for implantation of leads has improved to 95 percent at experienced centers.

Dr. Sholevar noted that, “Emerging data suggests that these systems may become the standard of care for most patients with dyssynchrony and any degree of heart failure as well as for most patients who require frequent pacing in the lower chambers of the heart.”

He added, “Including the additional lead to a cardioverter-defibrillator-implant procedure only modestly increases the cost of the intervention but makes all the difference in how the patient feels and lives.”

## CONTACT

To refer a patient to a Lourdes electrophysiologist, call  
**1-888-LOURDES (568-7337).**

<sup>1</sup> Cleland JGF, Daubert J-C, Erdmann E, et al. for the CARE-HF Study Investigators. The effect of cardiac resynchronization on morbidity and mortality in heart failure. *New England Journal of Medicine*. 2005;352:1539-1549.

# Lourdes News

## Lourdes Participates in Medicare Gainsharing Project

Our Lady of Lourdes Medical Center is one of 12 healthcare providers statewide and the only hospital in the tri-county area participating in a three-year Medicare project that allows hospitals to share with physicians some of the money saved by reducing costs.

The Physician Hospital Collaboration Demonstration will be the country's first major test of whether doctors will work with hospitals to cut costs and improve healthcare quality if they are given financial incentives, a concept called "gainsharing." The New Jersey Hospital Association (NJHA) is leading the program for the U.S. Centers for Medicare and Medicaid Services (CMS).

"This is an innovative program that may lend itself to providing some of the answers for health care reform," said **Alan Pope, MD**, vice president of medical affairs at Lourdes in Camden. "This is a program that will help drive us to continue to improve the efficiency and effectiveness of care." The program aims to better align how Medicare (and some private insurance plans) reimburse hospitals and doctors. Medicare reimburses hospitals at a fixed rate based on a patient's diagnosis, regardless of length of stay, while physicians receive payment for each procedure or day spent in the hospital.

The program aims to save the hospital and Medicare money through reduced patient stays, decreased re-admission rates and the avoidance of expensive technology where less costly technology will produce equivalent results. According to Dr. Pope, ways physicians can help reduce costs and improve quality include:

- Start surgeries on time.
- Facilitate timely discharges.
- Consider cost when selecting clinically equivalent pacemakers and joint replacement prostheses.
- Lead efforts to prevent infections that can lengthen hospital stays.

Participating doctors who achieve strong outcomes and manage to reduce costs may qualify for semi-annual financial incentives from the hospital, expected to range from \$90 to \$300 per patient, according to the NJHA. The payouts are expected to be far less than the overall savings the hospitals achieve through the program. The 500 physicians participating among the 12 hospitals (including approximately 60 high-admitters affiliated with Lourdes) will be measured against benchmarks for all physicians in the state.

While Lourdes doctors already do their best to offer the best care, Dr. Pope said the Medicare program provides "added incentive to spend extra time on the projects that could lead to more efficient care, less costly care but higher quality care." That could lead to decreases in cases of blood stream or urinary tract infections, ventilator-associated pneumonia and bed sores, as well as improved outcomes in surgical care and treatment of heart failure, pneumonia, heart attack and overwhelming infections, he said.

## Stroke Program Honored

Our Lady of Lourdes Medical Center has received the American Heart Association/American Stroke Association's Get With The Guidelines® – Stroke Silver Performance Achievement Award in recognition of the hospital's use of evidence-based protocols to provide patients with the best possible care.

Get With The Guidelines (GTWG) is a quality-improvement program that helps ensure hospitals' treatment of coronary artery disease, heart failure and stroke is aligned with the most current scientific guidelines and evidence-based therapies. The Silver Performance Award is conferred on hospitals that have achieved 12 consecutive months of 85 percent adherence to GTWG performance measures.

"Therapies and treatments recommended by the Get With The Guidelines program help improve patient outcomes, including reduced incidences of recurring events, complications and morbidity," said **Mark Bateman**, hospital CEO.

The Stroke Program at Lourdes is nationally recognized and has received a five-star rating for seven consecutive years from HealthGrades®, a leading independent quality-rating organization. In addition, the program received Healthgrades' 2008 Stroke Care Excellence Award and has been designated by the New Jersey Department of Health and Senior Services as a Primary Stroke Center.

