NEW DRUGS

Generic Coreg (Carvedilol) For Heart Disease

The U.S. Food and Drug Administration (FDA) has approved the first generic versions of GlaxoSmithKline’s carvedilol (Coreg). This drug is approved to treat high blood pressure, mild to severe chronic heart failure, and left ventricular dysfunction following a heart attack.

Multiple generic drug companies manufacture carvedilol tablets in four strengths: 3.125 mg, 6.25 mg, 12.5 mg, and 25 mg. Applications were approved for Actavis Elizabeth LLC, Apotex, Aurobindo, Caraco, Dr. Reddy’s, Glenmark, Lupin, Mylan, Ranbaxy, Sandoz, Taro, Teva, Watson, and Zydus.

The labeling of the generic products may differ from that of carvedilol because parts of the agent’s labeling are protected by patents and/or exclusivity.


Smallpox Vaccine (ACAM 2000)

A new vaccine has been licensed to protect people against smallpox. ACAM 2000 (Acambis) is indicated for the inoculation of those at high risk of exposure to smallpox, and it can be used in the event of a bioterrorist attack. It will be included in the Centers for Disease Control and Prevention’s (CDC’s) strategic national stockpile of medical supplies. The CDC considers the vaccine a Category A agent, with smallpox representing one of the greatest potential threats for harming public health.

Smallpox is caused by the variola virus, which emerged thousands of years ago. The only prevention is vaccination.

The vaccine is derived from the only other FDA-licensed smallpox vaccine (dried calf-lymph type [Dryvax, Wyeth]), approved in 1931. It is now in limited supply and is no longer manufactured.

Although smallpox vaccination ended in the U.S. in 1972, the military resumed vaccinations for at-risk personnel in 1999 after concluding that the disease posed a potential bioterrorism threat.

Because ACAM 2000 contains live vaccinia virus, care must be taken to prevent the virus from spreading from the inoculation site to other parts of the body and to other people.

(Source: FDA, September 1, 2007.)

Topical Human Thrombin (Evithrom)

Evithrom (Omrix), a blood-clotting protein used to help control bleeding during surgery, is the first human thrombin approved since 1954.

Evithrom is indicated when control of bleeding by standard surgical techniques is ineffective or impractical. The product is applied to the surface of bleeding tissue. It may also be used in conjunction with an absorbable gelatin sponge. Evithrom must not be injected into blood vessels.

In a clinical trial, it was comparable to cattle-derived thrombin in both safety and effectiveness.

(Source: FDA, August 28, 2007.)

Lanreotide (Somatuline): Orphan Drug for Acromegaly

Lanreotide acetate (Somatuline Depot Injection, Tercica) has been approved for the treatment of acromegaly, a rare and potentially life-threatening disease in adults. Abnormal secretion of growth hormone (GH) is commonly caused by a benign tumor in the pituitary gland.

This new treatment lowers the levels of certain hormones in the body, including GH and insulin-like growth factor. Excessive GH secretion can cause enlargement of the hands, feet, facial bones, and internal organs such as the heart and liver. If untreated, patients with acromegaly often have a shortened life span because of heart and respiratory diseases, diabetes mellitus, and colon cancer.

The safety and effectiveness of the product was determined in two pivotal clinical trials involving 400 patients.

(Source: FDA, August 30, 2007.)

Amlodipine/Olmesartan (Azor) For Hypertension

The FDA has approved a once-daily tablet combining amlodipine (Norvasc), a calcium-channel blocker, and olmesartan medoxomil (Benicar), an angiotensin-receptor blocker, for the treatment of hypertension. In clinical trials, Azor produced significant mean reductions in systolic and diastolic blood pressure. When compared with amlodipine 10 mg alone, Azor 10/40 mg resulted in a 53% greater reduction in systolic blood pressure.

Azor is indicated for the treatment of hypertension alone or with other anti-hypertensive agents. It is not indicated as initial therapy for hypertension.

(Source: Daiichi Sankyo, September 27, 2007, www.dsus.com.)

NEW INDICATIONS

Short-Course Levofloxacin (Levaquin) Therapy For Urinary Tract Infections and Pyelonephritis

The FDA has approved a five-day, once-daily IV and oral 750-mg regimen of levofloxacin (Levaquin, Ortho-McNeil, PriCara) for patients with complicated urinary tract infections (UTIs) and acute pyelonephritis (kidney infection).

This approval was based on results of a double-blind, randomized clinical trial. Since its U.S. introduction in 1996, levofloxacin has been used to treat adults with bacterial infections caused by susceptible pathogens, including acute bacterial sinusitis; acute bacterial exacerbation of chronic bronchitis; nosocomial pneumonia; community-acquired pneumonia, complicated skin and skin struc-
ture infections; mild-to-moderate, uncomplicated skin and skin structure infections; chronic bacterial prostatitis; mild to moderate complicated and uncomplicated UTIs (10-day regimen); complicated UTIs (five-day regimen); acute pyelonephritis; and post-exposure inhalational anthrax.

Levofoxacin is available in 250-mg, 500-mg and 750-mg doses in both IV and oral formulations.

(Source: FDA, September 17, 2007; www.levaquin.com.)

**Raloxifene (Evista): Reducing Breast Cancer Risk In Postmenopausal Women**

The FDA has approved raloxifene HCl (Evista, Eli Lilly) for reducing the risk of invasive breast cancer in postmenopausal women with osteoporosis and in postmenopausal women at high risk for invasive breast cancer. As a selective estrogen receptor modulator (SERM), raloxifene may act by blocking estrogen receptors in the breast.

In 1997, the FDA approved raloxifene for preventing osteoporosis in postmenopausal women; in 1999, it was approved for treating osteoporosis in postmenopausal women.

Because the drug can cause serious side effects, its benefits and risks should be carefully evaluated. It is not indicated for women with current or prior blood clots in the legs, lungs, or eyes; premenopausal women; and women who are or might become pregnant. The drug should not be taken with the cholesterol-lowering agent cholestyramine or with estrogens.

Raloxifene does not completely prevent breast cancer. Breast examinations and mammograms should be completed before women begin taking the drug and regularly thereafter.

(Source: FDA, September 14, 2007; www.hhs.gov/breastcancer.)

**Expanded Labeling For Alemtuzumab (Campath) In Leukemia Treatment**

The FDA has approved a supplemental biologics license application (sBLA) for alemtuzumab (Campath, Genzyme/Bayer HealthCare) and has granted regular approval for single-agent therapy for use in B-cell chronic lymphocytic leukemia. This agent was initially approved in 2001 under accelerated regulations.

Patients receiving alemtuzumab experienced higher overall and statistically significant complete response rates compared with patients receiving chlorambucil.

A boxed warning includes information on cytopenias, infusion reactions, and infections.

(Source: Genzyme/Bayer, September 20, 2007.)

**Nasal Influenza Vaccine (FluMist) Approved For Younger Children**

The nasal influenza vaccine FluMist (MedImmune) is now approved to include children between two and five years of age. Approval had previously been limited to healthy children five years of age and older and to adults up to age 49. The vaccine contains a weakened form of the live virus and is sprayed into the nose.

The CDC recommends that all children six months to 59 months of age receive a vaccination to protect against influenza. Until now, only two vaccines had been licensed in the U.S. for children younger than age five years: Fluzone (Sanofi-Pasteur) (for children older than six years of age) and Fluvirin (Novartis) (for children four years of age and older).

FluMist should not be administered to people with asthma or to children under five years of age with recurrent wheezing because of the potential for increased wheezing after the vaccine is administered.

Anyone who is allergic to FluMist’s components, including eggs or egg products, should not receive the vaccine.

(Source: FDA, September 19, 2007.)

**DRUG NEWS**

**Asthma Guidelines Updated**

For the first time in a decade, the National Asthma Education and Prevention Program has updated clinical guidelines for the diagnosis and management of asthma. New features include:

- an expanded section on asthma for children 5 to 11 years of age.
- information on medications.
- recommendations for patient education other than in a physician’s office.
- advice for controlling environmental factors that can cause symptoms of asthma.

The guidelines reaffirm that patients with persistent asthma need both long-term control and quick-relief medications. Also included are new recommendations:

- inhaled corticosteroids: considered the most effective long-term control medication for all age groups.
- leukotriene receptor antagonists and cromolyn: for long-term control.
- long-acting beta agonists: as adjunct therapy with inhaled corticosteroids.
- omalizumab (Xolair, Genentech): for severe asthma.
- albuterol, levalbuterol, and corticosteroids: for acute exacerbations.

(Source: National Heart, Lung, and Blood Institute, August 29, 2007.)

**FDA Alerts**

**Ceftriaxone (Rocephin)**

Important revisions have been made...
to the Contraindications, Warnings, and Dosage and Administration sections of the full prescribing information for ceftriaxone (Rocephin, Roche).

This new information addresses the interaction of ceftriaxone with calcium-containing products based on reports of fatal cases in neonates. Although no cases of ceftriaxone–calcium precipitates in patients other than neonates have been reported, the potential for this interaction exists in patients of any age.

Generally, fatalities have been associated with simultaneous administration of ceftriaxone and calcium-containing products; however, administration of the two products at different times and via different infusion lines has also been fatal. Therefore, ceftriaxone should not be mixed with calcium-containing products or administered in the same or different infusion lines or sites in any patient within 48 hours of each other.

The information in the August 2007 ceftriaxone label clarifies the labeling revision in May 2007 that first included information on this interaction.

(Source: FDA, September 2007.)

IV Haloperidol (Haldol)
The FDA has announced that the prescribing information for haloperidol (Haldol, generic versions) has been revised to include a new cardiovascular subsection in the Warnings section. Life-threatening arrhythmias (e.g., sudden death, QT prolongation, torsades de pointes) have been reported in patients treated with haloperidol, especially when the drug is administered intravenously or at doses higher than recommended.

Injectable haloperidol is approved only for intramuscular injection, although IV administration is known to be a fairly common off-label clinical practice.

A minimum of 28 cases of QT prolongation and torsades de pointes have been reported following intravenous administration and some have resulted in death.

(Sources: FDA, www.fda.gov; www.emedicine.com/recalls-alerts.asp#ra6.)

Fentanyl Buccal Tablets (Fentora)
Cephalon has issued two “Dear Health Care Professional” letters to inform prescribers and other health care providers of important safety information regarding fentanyl buccal tablets (Fentora). Fentanyl buccal tablets are indicated only for breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for underlying persistent cancer pain.

Serious adverse events, including deaths, have occurred in patients treated with Fentora. The deaths occurred as a result of improper patient selection (e.g., use in patients not tolerant to opioid therapy), improper dosing, and/or improper product substitution. Appropriate patient selection and proper dosing and administration of Fentora are essential to reduce the risk of respiratory depression.

Key safety information is as follows:

- Fentora should not be used in patients who are not tolerant to opioid therapy.
- It should be used only for labeled indications.
- It should not be prescribed for patients with acute pain, postoperative pain, headache, migraine, or sports injuries.
- Fentora is not a generic version of Actiq or other fentanyl-containing products and should not be substituted.
- For unrelieved breakthrough pain, patients should not take more than two tablets per episode of breakthrough pain.
- Patients must wait at least four hours before treating another episode of breakthrough pain with Fentora.

(Sources: FDA, www.fda.gov; www.emedicine.com/recalls-alerts.asp#ra6.)

Shire has announced the voluntary market withdrawal of a limited amount of its Daytrana patch, which is used to treat attention-deficit hyperactivity disorder. Only Daytrana packages with an expiration date of March 31, 2009, or earlier and packages with lot numbers 2563511, 2563611, and 2570411 are affected. Shire is taking this step because of feedback from patients and caregivers who have experienced difficulty removing the release liner from some of the patches. The company expects the patches that are not subject to the withdrawal and those that have been manufactured via an enhanced process to offer improved ease of use when the release liner is peeled off the patch. The current supply levels of Daytrana are sufficient to ensure that patients can have their prescriptions filled with the easier-to-use patch.

(Source: Shire, September 4, 2007; www.shire.com.)

Tamoxifen (Nolvadex)
Benefits Bipolar Manic Phase
In a new study, tamoxifen citrate (Nolvadex, AstraZeneca), best known as a treatment for breast cancer, dramatically reduced symptoms of the manic phase of bipolar disorder more quickly than many standard medications for the mental illness. By the end of the study, 63% of the patients taking tamoxifen had reduced manic symptoms, compared with only 13% of those taking a placebo. Patients taking tamoxifen responded by the fifth day.

Researchers at the National Institute of Mental Health (NIMH) explained that tamoxifen blocks an enzyme called protein kinase C (PKC), which regulates activities in brain cells. The enzyme is thought to be overactive during the manic phase of bipolar disorder.

By pointing to PKC as a target for new
drugs, the study raises the possibility of developing faster-acting treatments for the manic phase of the illness. Current medications for the manic phase generally take more than a week to begin working.

However, it is not clear whether tamoxifen will become a treatment of choice; it blocks estrogen, which makes it useful as a treatment for breast cancer—but it may cause endometrial cancer if it is taken over long periods of time.

(Source: www.nimh.nih.gov; Bipolar Disord, September 2007.)

**Blocking Formation of Toxic Plaques Might Help Type-2 Diabetes**

Amid growing evidence that the same abnormal clumping of proteins in Alzheimer’s disease also contributes to type-2 diabetes, scientists are reporting the discovery of a potent new compound that reduces formation of these amyloid plaques. The report cites evidence correlating increases in amyloid formation in the pancreas with increases in severity and in the rate of progression of type-2 diabetes.

Deposits of the abnormal protein damage and destroy insulin-producing islet cells in the pancreas. Researchers have been seeking potential new medications that block formation of an abnormal, misfolded protein called islet amyloid polypeptide (IAPP), which may play a key role in the cell destruction.

In this study, the investigators found that changing a single amino acid in the IAPP’s structure transformed it from one of the most potent amyloid-forming substances into a powerful inhibitor of amyloid formation. In laboratory studies, the mutant IAPP significantly reduced the amount of amyloid formed.

In addition to opening the door for better IAPP inhibitors in type-2 diabetes, the findings provide potentially important insights into the formation and treatment of amyloid plaques in Alzheimer’s disease, Parkinson’s disease, and other conditions, the researchers say.

(Source: J Am Chem Society, September 5, 2007.)

**Fixed-Dose Regimens Improve Adherence**

Hypertension, diabetes, and other conditions mean that patients must manage anywhere from two to a multitude of medications. It’s no wonder that some find it difficult to stick with their treatments. Polypharmacy and complexity of regimens are two determinants of poor compliance.

Fixed-dose regimens may improve compliance by reducing pill burden and some of the complexity. Researchers have found that fixed-dose combination regimens reduced the risk of noncompliance by as much as 26%, compared with “free-drug” combinations (giving individual components concomitantly).

(Source: Am J Med 2007;120:713–719.)

**Dangerous Interactions: Valproate (Depacon) And Meropenem (Merrem)**

Valproate sodium (Depacon, Abbott) and meropenem (Merrem, AstraZeneca) are often used in intensive care units to treat seizures and serious infections. In an 18-month study at University Hospital Gasthuisberg in Leuven, Belgium, 39 patients simultaneously receiving both drugs demonstrated an alarming interaction—an average drop of 66% in valproate plasma concentrations within 24 hours in 19 patients who had undergone daily plasma monitoring.

The clinical impact of the interaction could not be assessed in 19 patients who died or whose charts were incomplete. In the remaining 20 patients, the interaction was shown to be probable in 16 patients and possible in four, also contributing to electroclinical deterioration in 11 of the patients.

In one patient, valproate plasma concentrations dropped from 119 to 34 mg/L and his seizures increased. When meropenem was stopped, concentrations returned to the therapeutic range and the patient’s seizures were controlled.

Eight patients had seizures, and two had myoclonia. Meropenem was reported to be the causative agent in most of the cases; however, other carbapenems were also involved. The researchers concluded that the interaction can be considered a drug-class effect.

(Source: Ann Pharmacother 2007;41:1130–1136.)

**Selenium and Diabetes Risk**

Although some animal studies have suggested that selenium supplements may help prevent vascular complications in patients with diabetes, findings from the Nutritional Prevention of Cancer trial in 1,202 patients from dermatology clinics suggest otherwise. Not only did selenium not help, it might have even heightened the risk of diabetes.

None of the patients had type-2 diabetes at the baseline evaluation. They were given 200 mcg of selenium or placebo daily in a clinical trial designed to assess the effects of selenium on skin cancer. During an average follow-up period of 7.7 years, diabetes developed in 58 selenium recipients and in 39 placebo recipients. The risk of diabetes was consistently higher in the selenium group within all subgroups of baseline age, sex, smoking status, and body mass index.

The researchers say that to their knowledge, this was the largest completed randomized clinical trial to date that has examined the efficacy of selenium supplementation alone in preventing type-2 diabetes. They add that evidence for potential mechanisms that explain their findings is limited. How-
over, some research has shown adverse health effects from long-term exposure to selenium. For one thing, dietary selenium may adversely affect growth hormone metabolism by suppressing the production of insulin-like growth factor I, which influences glucose homeostasis.

Data from animal models suggest that high-selenium diets may stimulate the release of glucagon, thus inducing hyperglycemia, they add.

The evidence also indicated that selenium supplementation might have a role in cancer prevention.


**Amiodarone and Pacemakers**

For patients with new-onset atrial fibrillation, amiodarone tablets (Pacerone, Upsher-Smith; Cordarone, Wyeth) may increase the risk of bradycardia, thus necessitating the insertion of a pacemaker—and the risk is higher in women.

Researchers from McGill University, Beth Israel Deaconess Medical Center, the University of Ottawa Heart Institute, and Rhode Island Hospital studied 973 patients with atrial fibrillation who were enrolled in the Fibrillation Registry Assessing Costs, Therapies, Adverse events, and Lifestyle (FRACTAL). Of those patients, 85 received a pacemaker during the two-year follow-up period.

Amiodarone was associated with an increased need for pacemaker insertion after adjustments were made for age, sex, atrial flutter, coronary artery disease, congestive heart failure, and hypertension. Age and atrial flutter were also independently associated with an increased risk of pacemaker implantation. The association with atrial flutter was “unexpected,” the researchers say. The risk tended to be higher with doses greater than 200 mg/day.

Other antiarrhythmic medications (e.g., sotalol [Betapace, Berlex]) or rate-control medications (e.g., beta blockers) were not linked to the risk. The researchers point out that amiodarone has a much longer half-life—more than 30 days—compared with less than one day for the other medications.

Women were at a significant risk of needing a pacemaker; studies suggest that the risk of tachyarrhythmia associated with amiodarone is also higher in women. Because the bradycardic effect of amiodarone is dose-related, it might be prudent, the investigators advise, to use lower loading and maintenance doses, particularly in elderly women.

(Source: *Arch Intern Med* 2007;167: 1648–1653.)

**Second-Line Drugs For Bronchitis**

Second-line antibiotics may be more effective than first-line antibiotics for patients with acute exacerbations of chronic bronchitis, say researchers from Athens, Greece.

Analyzing data from 12 randomized, controlled trials involving 2,261 patients, the team found that first-line antibiotics (e.g., amoxicillin, trimethoprim/sulfamethoxazole [Bactrim, Women First], ampicillin, and doxycycline [Vibramycin, Pfizer]) were associated with lower rates of successful treatment compared with second-line drugs (e.g., amoxicillin/clavulanic acid [Augmentin, Glaxo-SmithKline]), macrolides, second-generation and third-generation cephalosporins, and quinolones). There were no differences among the regimens in terms of adverse effects such as diarrhea.

The observed clinical advantage of the second-line antibiotics should be “very carefully interpreted,” the researchers say. For one thing, the selected trials did not provide adequate clinical information on whether the enrolled patients had risk factors for poor outcomes, such as age over 65 or comorbid illness (especially cardiac disease). At least half of the trials enrolled hospitalized patients; it’s more likely that they would have a higher degree of pulmonary impairment and comorbidities requiring advanced antibiotics.

Admittedly, the findings seemed to “contravene the attempt to preserve new antibiotics and to prevent further development of resistance,” the researchers say. But they add that “treatment directed toward resistant pathogens with adequately effective antimicrobial drugs” was expected to prevent a lack of response to therapy, thus avoiding prolonged hospitalization and repeated courses of antibiotics.

(Source: *Chest* 2007;132:447–455.)

**More Aggressive Statins For the Elderly**

More elderly patients at risk for congestive heart failure are getting aggressive statin therapy when they need it. Researchers from Kaiser Permanente Center for Health Research in Portland, Oregon, say that the 2004 update to the National Cholesterol Education Program Adult Treatment Panel III guidelines and the corresponding revision of internal guidelines in the large health maintenance organization they studied resulted in more patients receiving minimal-guideline statin therapy.

The investigators analyzed records of 14,425 elderly patients who received statins in 2003 and 19,422 who received treatment in 2005. Among patients at very high risk, 10% of new statin users and 19% of ongoing users received aggressive therapy in 2005, compared with 3% and 12% in 2003.

Overall, among new statin users, 85% at high risk for heart failure received minimal-guideline therapy in 2005, compared with 65% in 2003. Of ongoing users,
78% received minimal-guideline therapy in 2005, compared with 59% in 2003.

The increase in the proportion receiving minimal-guideline therapy did not mean that more patients attained their low-density lipoprotein-cholesterol (LDL-C) goals, however—perhaps because older patients rarely received intensive statin therapy, the researchers suggest. Even though aggressive therapy was more common after the guidelines were revised, only a minority of patients received it, even among those at very high risk for congestive heart failure. Neither the updated guidelines nor Kaiser Permanente’s revised guidelines explicitly recommend intensive therapy, the researchers say, “opting instead for a recommendation of therapy expected to decrease LDL-C by 30% to 40%.”

(Source: Am Heart J 2007;154:554–560.)

**Statins versus Good Intentions with Diet**

Health care providers might be wondering whether their patients will use statin therapy as an excuse to change their diet—for the worse. No need to worry, say researchers from Mount Sinai, Columbia University, Veterans Affairs Medical Center and New York University, and Weill Medical College, all in New York; and the Mayo Clinic in Rochester, Minnesota.

Seventy-one patients with new prescriptions for statins to prevent cardiovascular disease were interviewed, first at the time of prescription and then again three and six months later. The investigators observed no evidence that taking statins—a trend toward a healthier diet, patients who reported lower adherence to statins—a trend toward a healthier diet, cutting back on fats, and boosting their intake of fruits, vegetables, and fiber. This apparent discordance may contribute to poor adherence, the researchers suggest, and “may reflect an unintended consequence of the increasing medicalization of hyperlipidemia.” They see a need for improved communication before and after statin therapy starts.

Over time, attitudes toward both dietary change and statin therapy tended to become more positive. Further, the researchers saw a definite trend among patients who reported lower adherence to statins—a trend toward a healthier diet, cutting back on fats, and boosting their intake of fruits, vegetables, and fiber. (Source: Mayo Clin Proc 2007;82:951–953.)

**Not All Clavicular Fractures Are Treated Equally**

The youngest and the oldest patients who arrive at emergency departments (EDs) are unlikely to receive a narcotic analgesic for a broken clavicle, according to a retrospective analysis of 7,199 ED visits over nine years from Morristown Memorial Hospital in New Jersey.

Overall, opiate prescriptions were issued to few patients—and only 18% of patients from birth to three years of age and 25% of patients 70 years of age and older received them. By contrast, 36% to 40% of patients from nine to 69 years of age received prescriptions.

The researchers say that their findings echo those of other studies in which the youngest children were less likely than older children to receive analgesia for various painful events, such as burns, fractures, and sickle-cell crisis. It is possible that the very young and the very old perceive the pain of clavicular fractures differently, but the researchers say that the rationale for withholding narcotics for those patients needs further evaluation.


**Layering Anesthesia May Benefit Deep Wounds**

Topical anesthesia can eliminate the need for an anesthetic injection. “Layering,” a technique for administering topical anesthetics, has been studied mainly in children and in small wounds, but a Harvard study suggests that the practice might have a broader application.

Researchers compared a sequential layered application of anesthetic ingredients with 2% lidocaine infiltration in 100 patients with lacerations that needed to be sutured.

Three ingredients are usually used: lidocaine, epinephrine, and tetracaine. The researchers used only topical lidocaine and epinephrine (TLE) to limit toxicity. They soaked a piece of cotton just large enough to cover the laceration, plus 2 mm of surrounding skin, with TLE, placed it on the wound for 10 to 15 minutes, and then removed it. They then placed a second piece of TLE-soaked cotton deeper inside the wound for 10 to 15 minutes and removed it.

For deeper wounds, they packed a third layer farther into the wound. When the wound edges showed a 3-mm-wide or greater area of vasoconstrictive pallor, the wound was considered anesthetized.
and ready for suturing.

In the controls, the time necessary for adequate anesthesia ranged from 1 to 12 minutes (mean, 5 minutes). The amount of lidocaine needed to achieve adequate anesthesia varied from 10 to 340 mg.

In the layered-anesthesia group, the time needed for anesthesia varied from 20 to 40 minutes, (mean, 29 minutes). One to four layer applications were needed. Half of the patients required three layers. Deeper lacerations were more time-consuming.

Although it took longer for the anesthesia to work, the TLE patients reported less pain and 66% of them reported no pain, compared with 0% of controls. On follow-up, 95% of the TLE patients rated their experience as “excellent,” compared with 5% of the control patients.

Is layering worth the time? The researchers say yes: the technique eliminated painful injections, the risk of needle injury, and distortion of infiltrated wound tissue. They also felt that patient satisfaction justified the extra time. They waited 10 to 15 minutes for anesthesia to take effect for each layer. They also thought that the time could be reduced without compromising the effectiveness of anesthesia.


**NEW MEDICAL DEVICES**

**Marvin M. Goldenberg, PhD, RPh, MS**

**Name:** Now Malaria Test

**Manufacturer:** Binax, Inc./Inverness Medical Innovations, Scarborough, Maine

**Approval Date:** June 27, 2007

**Use Classification:** This rapid, three-step test is used for the differential diagnosis of malarial infections. It provides results in 10 minutes, allowing for accurate treatment and improved patient outcomes.

**Description:** The test uses two antibodies that have been immobilized across the test strip. One antibody is specific for the histidine-rich protein II antigen of *Plasmodium falciparum* (*P.f.* HRPII). The other antibody is specific for an antigen that is common to *P. falciparum*, *P. vivax*, *P. ovale*, and *P. malariae*.

A procedural control line is also immobilized across the test strip and always appears in area C of the test window if the test has been performed correctly. Whole blood (15 microliters) is applied to a sample pad impregnated with colloidal gold-labeled antibodies, which are directed against the malarial antigens. When a positive sample is applied, malarial antigens bind to the gold-conjugated antibodies in the sample pad. Reagent is then added and allows the immune complexes formed to migrate along the test strip, where they are captured by the immobilized antibodies. When capture occurs, one or two pink lines form in the test window. When a negative sample is applied, only the control line appears.

**Purpose:** This rapid immunodiagnostic assay detects circulating *P. falciparum* antigen and an antigen that is common to all four species of malaria—*P. falciparum*, *P. vivax*, *P. ovale*, and *P. malariae*—in whole blood.

**Benefit:** In addition to its rapid readout, the test was 95% accurate, compared with standard microscopic diagnosis.

**Precautions:** Optimal results are obtained by strict adherence to this protocol. Reagents must be added carefully to maintain precision and accuracy. Used cards should be considered to be biohazardous and should not be reopened or reused. Biological contamination of dispensing equipment, containers, or reagents can lead to false results. Established precautions should be observed against microbiological and serologic hazards in specimen handling and disposal and for all procedures.

**Sources:** FDA, June 26, 2007; www.fda.gov; http://binax.com/uploads/malaria_pi_6_1_06_001.pdf

**Name:** Fraxel “Re:pair” Laser System

**Manufacturer:** Reliant Technologies, Inc., Mountain View, Calif.

**Approval Date:** July 2, 2007

**Use Classification:** The laser system is used for ablation, coagulation, and skin resurfacing.

**Description:** The system treats a portion of the skin’s surface and leaves the surrounding areas intact to allow for rapid healing. With fractional deep dermal ablation treatment, the skin is ablated and coagulated in deep (up to 1.6-mm) columns called microscopic treatment zones. With the laser’s high-speed optics, these zones can be spaced across the skin’s surface to provide even, thorough tissue tightening for effective resurfacing.

**Purpose:** The laser system is indicated for contracting and tightening of the skin.

**Benefit:** The Fraxel Re:pair laser combines the benefits of conventional carbon dioxide resurfacing with the safety of fractional photothermolysis. The treatment provides dramatic results without the considerable risks and recovery time associated with traditional carbon dioxide lasers and surgical procedures.

The process is safe for treating even delicate areas, such as the neck and chest, as a result of the tissue-sparing design. In contrast, conventional bulk ablative laser skin resurfacing ablates 100% of the epidermis and is therefore too aggressive to treat the neck and chest; that procedure often leaves an undesirable line of demarcation, resulting in hypopigmentation.

For patients who have spent years in the sun or smoking and who wish to have tighter, smoother, and more even skin...
This laser is safe and effective.

**Source:** www.pharmacyonesource.com; www.reliant-tech.com; www.laserfocusworld.com

**Name:** RTX3370 Telehealth Monitor

**Manufacturer:** RTX Healthcare, Noerreundby, Denmark

**Approval Date:** August 23, 2007

**Use Classification:** The Telehealth Monitor is a wireless, interactive device designed to improve the way health care is provided to elderly patients residing outside a hospital who have chronic diseases (e.g., heart failure, chronic obstructive pulmonary disease, diabetes).

**Description:** The monitor collects vital signs from peripheral devices and information from patient questionnaires and transmits the data directly to the client’s own clinical information system. The peripheral devices include scales, blood pressure monitors, blood glucose meters, peak flow meters, and pulse oximetry meters. Patients’ vital signs such as weight, blood pressure, and blood glucose levels are transmitted to the monitor.

**Purpose:** The device represents an open standard approach to improve health care for patients worldwide by transmitting patients’ vital signs to a monitor.

**Benefit:** The monitor is simple and intuitive to use for elderly patients. The device is designed to provide less expensive, faster, and more reliable health care solutions. The monitor includes a large easy-to-read color display, simple buttons, and a speaker for vocalization by the patient.

**Sources:** www.clinicitmanager.com; www.medcompare.com; www.rtx.dk

**Devices in the News**

**Pump Recall (June 21, 2007)**

Baxter Healthcare and the FDA notified health care professionals and consumers of a Class I recall of Colleague CX Volumetric Infusion Pumps (Models 2M8151 and 2M8153), Colleague CX Volumetric Infusion Pumps (Models 2M8161 and 2M8163), and Flo-Gard Volumetric Infusion Pumps (Models 2M8063 and 2M8064).

The firm had found falsified repair, inspection, and test data sheets, which included electrical safety data for the devices. Pumps that were sent to be serviced, repaired, or corrected might have been returned unserviced. This omission can result in overinfusion, underinfusion, failure to detect an upstream or downstream occlusion, electrical shock hazard, failure to detect air in line, and malfunctions resulting in an interrupted therapy, which can lead to death.

Baxter requested its customers to remove the affected pumps from service and to send them back for another inspection. The company agreed to provide loaner pumps free of charge.

Class I recalls are the most serious type of recall because of the possibility of serious injury or death.

**Sources:** www.pharmacyonesource.com; www.fda.gov/cdrh/recalls/recall-062107.html

**Stent Controversy (August 2007)**

Boston Scientific Corporation’s five-year, final results from its Taxus II clinical trial revealed continued long-term safety and efficacy for the Taxus paclitaxel-eluting stent system. The Taxus stent was not associated with any additional stent thrombosis between the fourth and fifth years, whereas a control patient receiving a bare-metal stent experienced one stent thrombosis during this same period. This marks the third consecutive year of Taxus II follow-up with no stent thrombosis seen in the Taxus stent patient group. These results warrant possible further study to see whether they indicate longer-term trends.

**Sources:** www.fiercebiotech.com; www.bostonscientific.mediaroom.com