

ON THE BEAT

Cardiologists on the Move

Dr. Lynn H. Harrison Jr., credited with revitalizing the cardiac surgery program at the University of Massachusetts Memorial Medical Center, has joined Baptist Health South Florida, a six-hospital health care system based in Miami.



DR. LYNN H. HARRISON

Dr. Harrison was brought on board at UMass Memorial in January 2006 as chief of the cardiac surgery division. The division's elective cardiac surgery program had been shut down for 2 months in 2005 because mortality rates for coronary artery bypass graft had exceeded the state average. Dr. Harrison spearheaded department changes, including the standardization of pre- and postop management, that led to its current ranking as one of the top 100 U.S. programs.

The most important change, he told *CARDIOLOGY NEWS*, was "rounding together as a team, including surgeons, nurse practitioners, physician assistants, surgical residents, clinical pharmacists, and students on every patient every day." Morbidity and mortality rates plummeted, he recalled, "and we were awarded the highest rating for clinical excellence by the Society of Thoracic Surgeons."

Dr. Harrison serves as clinical director

of cardiac surgery for Baptist Health's newly formed Cardiac and Thoracic Surgery Group.

Dr. Harrison received his medical degree from the University of Oklahoma in Oklahoma City. He trained in general and cardiothoracic surgery at Duke University in Durham, N.C. Prior to joining UMass, he was professor of surgery and chief of cardiothoracic surgery at Louisiana State University, New Orleans.

Dr. Mark E. Anderson was named head of the internal medicine department at the University of Iowa Roy J. and Lucille A. Carver College of Medicine and UI Hospitals and Clinics. Dr. Anderson, associate director of the university's cardiovascular research center, is a cardiac electrophysiologist whose research has focused on a signaling protein, calmodulin kinase II, and its role in heart rhythm abnormalities and heart muscle enlargement. His clinical interests include pacemakers, defibrillators, and catheter ablation therapy. He joined the UI faculty in 2005 as professor of internal medicine and director of the cardiology division.



DR. MARK E. ANDERSON

He received his medical degree from the University of

Minnesota, Minneapolis, and completed an internship and residency in internal medicine at Stanford (Calif.) University, where he also trained in cardiology and clinical cardiac electrophysiology. He was a faculty member at Vanderbilt University, Nashville, Tenn., from 1996 to 2005.

Abbott Expands Stent Trial

Abbott has announced the expansion of its Xience V USA postapproval study to allow more than 2,000 of its patients to cross over into the Dual Antiplatelet Therapy (DAPT) 20,000-patient trial.

Originally designed to study 5,000 pa-

tients, Xience V USA's expansion will allow enrollment of an additional 3,000 patients. The trial's primary end point is a measure of stent thrombosis every year out to 5 years, as defined by the Dublin/Academic Research Consortium.

DAPT, a consortium of pharmaceutical and medical device companies (including Abbott), is designed to determine the duration, safety, and efficacy of dual antiplatelet therapy to protect patients from stent thrombosis and major adverse cardiovascular and cerebrovascular events after stent implantation.

—Jane Locastro

PLAVIX

(clopidogrel bisulfate) tablet, film coated

clinical trials are listed below regardless of relationship to PLAVIX. In general, the incidence of these events was similar to that in patients receiving aspirin (in CAPRIE) or placebo + aspirin (in the other clinical trials).

Body as a whole: Allergic reaction, necrosis ischemic. **Cardiovascular disorders:** Edema generalized. **Gastrointestinal system disorders:** Peptic, gastric or duodenal ulcer, gastritis, gastric ulcer perforated, gastritis hemorrhagic, upper GI ulcer hemorrhagic. **Liver and Biliary system disorders:** Bilirubinemia, hepatitis infectious, liver fatty. **Platelet, bleeding and clotting disorders:** hemarthrosis, hematuria, hemoptysis, hemorrhage intracranial, hemorrhage retroperitoneal, hemorrhage of operative wound, ocular hemorrhage, pulmonary hemorrhage, purpura allergic, thrombocytopenia. **Red blood cell disorders:** Anemia aplastic, anemia hypochromic. **Reproductive disorders, female:** Menorrhagia. **Respiratory system disorders:** Hemothorax. **Skin and appendage disorders:** Bullous eruption, rash erythematous, rash maculopapular, urticaria. **Urinary system disorders:** Abnormal renal function, acute renal failure. **White cell and reticuloendothelial system disorders:** Agranulocytosis, granulocytopenia, leukemia, leukopenia, neutropenia.

Postmarketing Experience

The following events have been reported spontaneously from worldwide post-marketing experience:

- **Body as a whole:**
 - hypersensitivity reactions, anaphylactoid reactions, serum sickness
- **Central and Peripheral Nervous System disorders:**
 - confusion, hallucinations, taste disorders
- **Hepato-biliary disorders:**
 - abnormal liver function test, hepatitis (non-infectious), acute liver failure
- **Platelet, Bleeding and Clotting disorders:**
 - cases of bleeding with fatal outcome (especially intracranial, gastrointestinal and retroperitoneal hemorrhage)
 - thrombotic thrombocytopenic purpura (TTP) – some cases with fatal outcome – (see **WARNINGS**)
 - agranulocytosis, aplastic anemia/pancytopenia
 - conjunctival, ocular and retinal bleeding
- **Respiratory, thoracic and mediastinal disorders:**
 - bronchospasm, interstitial pneumonitis
- **Skin and subcutaneous tissue disorders:**
 - angioedema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, lichen planus
- **Renal and urinary disorders:**
 - glomerulopathy, increased creatinine levels
- **Vascular disorders:**
 - vasculitis, hypotension
- **Gastrointestinal disorders:**
 - colitis (including ulcerative or lymphocytic colitis), pancreatitis, stomatitis
- **Musculoskeletal, connective tissue and bone disorders:**
 - myalgia

OVERDOSAGE

Overdose following clopidogrel administration may lead to prolonged bleeding time and subsequent bleeding complications. A single oral dose of clopidogrel at 1500 or 2000 mg/kg was lethal to mice and to rats and at 3000 mg/kg to baboons. Symptoms of acute toxicity were vomiting (in baboons), prostration, difficult breathing, and gastrointestinal hemorrhage in all species.

Recommendations About Specific Treatment

Based on biological plausibility, platelet transfusion may be appropriate to reverse the pharmacological effects of PLAVIX if quick reversal is required.

DOSAGE AND ADMINISTRATION

Recent MI, Recent Stroke, or Established Peripheral Arterial Disease

The recommended daily dose of PLAVIX is 75 mg once daily.

Acute Coronary Syndrome

For patients with non-ST-segment elevation acute coronary syndrome (unstable angina/non-Q-wave MI), PLAVIX should be initiated with a single 300-mg loading dose and then continued at 75 mg once daily. Aspirin (75 mg–325 mg once daily) should be initiated and continued in combination with PLAVIX. In CURE, most patients with Acute Coronary Syndrome also received heparin acutely (see **CLINICAL STUDIES** in the full prescribing information).

For patients with ST-segment elevation acute myocardial infarction, the recommended dose of PLAVIX is 75 mg once daily, administered in combination with aspirin, with or without thrombolytics. PLAVIX may be initiated with or without a loading dose (300 mg was used in CLARITY; see **CLINICAL STUDIES** in the full prescribing information).

Pharmacogenetics

CYP2C19 poor metabolizer status is associated with diminished response to clopidogrel. The optimal dose regimen for poor metabolizers has yet to be determined. (See **CLINICAL PHARMACOLOGY: Pharmacogenetics** in the full prescribing information.)

No dosage adjustment is necessary for elderly patients or patients with renal disease. (See **CLINICAL PHARMACOLOGY: Special Populations** in the full prescribing information.)

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CDC Updates Its Antiviral Guidance for Flu Season

BY HEIDI SPLETE

The Centers for Disease Control and Prevention has updated its guidelines for using antiviral medications to treat the seasonal and pandemic influenza A(H1N1) viruses, according to the CDC Web site.

The updated recommendations include guidance for clinicians about the following:

► **Treating children younger than age 1 year.** Oseltamivir (Tamiflu) is not approved by the Food and Drug Administration for use in children younger than 1 year of age. But given this age group's increased risk for complications from the H1N1 virus, the CDC recommends a 5-day antiviral treatment dose with oseltamivir of 25 mg twice daily for children aged 6-11 months, 20 mg twice daily for children aged 3-5 months, and 12 mg twice daily for children younger than 3 months.

The CDC's recommendations for 10-day prophylaxis with oseltamivir are 25 mg once daily for children aged 6-11 months, and 20 mg once daily for children aged 3-5 months, but oseltamivir is not currently recommended for prophylaxis for children younger than 3 months unless the situation is deemed critical.

The FDA issued an Emergency Use Authorization in April 2009 for the emergency use of oseltamivir in children younger than 1 year old.

► **Dispenser measurements.** Clinicians and pharmacists are cautioned that an oral dosing dispenser that comes with Tamiflu for oral suspension shows dose measurements in 30-mg, 45-mg, and 60-mg increments. These measurements use mg and match those currently recommended by the CDC for treatment or chemoprophylaxis against H1N1 infection, but the prescription instructions may be listed in mL or tsp, which can lead to dosing errors.

► **Patients with neuromuscular or neurocognitive disorders.** The revised recommendations for individuals who might benefit most from early treatment with antiviral therapy include patients with disorders that can increase the risk for aspiration, such as spinal cord injuries, seizure disorders, cognitive dysfunction, and other neuromuscular disorders, plus any disorders that "can compromise respiratory function or the handling or respiratory secretions."

The CDC stated that its guidance will be updated as needed. For the latest information on the CDC's flu recommendations, visit cdc.gov or flu.gov. ■