

Kentucky Chapter Update

A Newsletter for the Members of Kentucky ACEP



Summer 2010 Issue

Government Affairs

Wes Brewer, MD, FACEP

Much of this year's Leadership and Advocacy conference in Washington D.C. this spring was consumed with trying to sort out how the healthcare reform process will affect our everyday practice. It seems as if everyone had an opinion but no real answers. The flow of speculation or information was like trying to sip tea from the end of a firehose! There was general consensus that most politicians and their staff are suffering from "healthcare reform fatigue" and it is likely that there will be no serious effort from either side of the political spectrum to change anything until after the midterm elections. After more than a year of nothing but healthcare debate on the hill they are anxious to move on and work on other things. It is of note that the majority of changes will not take effect until 2014, but most of the experts agreed that year will be very challenging. Much of the frustration with the coming reforms stems from the fact that a significant number of changes are not defined but left to the Secretary of Health and Human Services to impose by administrative regulation. It is not clear if the rules of the game change each time we get a new Secretary.

During the debate prior to the passage of the legislation, Senator McConnell in opposing the reforms as presented, spoke on 50 or more separate occasions about malpractice reform as part of the solution to our healthcare problems. I was excited to have the opportunity to meet with his staff, hoping to explore plans for this topic further, but alas, hopes were dashed when his aides explained that he had no plan for malpractice reform. The clarification was that he thought it would be a good idea to encourage individual states the explore liability reform. Oh well, back to the drawing board.



ACEP Responds to HealthGrades Report

For Immediate Release
June 24, 2010
Contact: [Laura Gore](#)
202-728-0610 x3008

Kentucky Chapter ACEP



Barbara Reynolds, MD, FACEP
President

Ashlee Melendez, RN, MSPH
Executive Director

Contact us:
ky.chapter@acep.org

Phone: 502-852-7874
Fax: 502-852-0066

410-733-4109

www.acep.org

Cautions that Inpatient Mortality is Not an Emergency Department Measure

Washington, DC – A new report from HealthGrades analyzes mortality data from the records of Medicare patients who were admitted in hospitals across the United States, but is not a measure of emergency care, according to the American College of Emergency Physicians (ACEP).

“Efforts to gather data on emergency medicine are critical, especially as the nation embarks on health care reform,” said Dr. Angela Gardner, president of ACEP. “This new report makes several critical points about the negative effects of delays in care and anticipated increases in emergency visits. However, the mortality rates in this report are a measure of inpatient hospital care, not just emergency care.”

Dr. Gardner also raised concerns about using the one measure of mortality data, which also could be biased against hospitals that treat the sickest patients.

“Less biased measures of emergency care would include the timely flow of patients, appropriate medical treatment per diagnosis and accuracy of diagnosis,” said Dr. Gardner. “While emergency physicians appreciate the objective of giving awards to emergency departments, it’s important to base the awards on data related to emergency care.”

The report’s statement -- “This Emergency Medicine Excellence Award is intended as a proxy for the effectiveness of a hospital’s multi-disciplinary teamwork and its ability to diagnose, triage and provide timely care to their patients.” -- is a more appropriate conclusion for the analysis.

ACEP is a national medical specialty society representing emergency medicine. ACEP is committed to advancing emergency care through continuing education, research and public education. Headquartered in Dallas, Texas, ACEP has 53 chapters representing each state, as well as Puerto Rico and the District of Columbia. A Government Services Chapter represents emergency physicians employed by military branches and other government agencies.



KACEP Officer Nominations and Committee Volunteers

“You only get out of something what you put into it” is one of the many clichés relating to participation. It is, however, true. Taking part in a process is what makes it better and meaningful for not only the participants but for the whole. This refers to participation in elections, committees, meetings and other activities.

It has been wonderful to see our membership numbers grow well over the 300 mark. Maintaining this level of membership will allow us to have greater representation at ACEP as well as allow us to be more effective at home.

What would be even better would be for more of our members to participate at the committee level and/or on the Board. Most of our “committees” are only one member deep. Anyone who joins a committee would have a significant role and find their time well spent for themselves as well as our specialty.

At our annual meeting, on November 18, 2010, please consider running for election or ask to be assigned to a committee. Every member has a voice and a place. Our chapter would be stronger if more of our voices were heard. This is your opportunity to make a difference.

If you would like to run for a Board position, Councillor, or sit on a committee, please submit your name, contact information, and bio to [Ashlee Melendez](#) prior to October 20, 2010. President, Vice President, and Councillors are two year terms, the rest of the terms are one year.

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David W. Brewer, MD, FACEP



Emergency Preparedness and Disaster Planning

L. Barrett Bernard, MD

Chair, Emergency Disaster and Preparedness

The H1N1 pandemic has continued at a low baseline. In follow-up, the HHS has just announced an end to the public health emergency associated with the H1N1 flu strain. However, researchers in Hong Kong report the virus has remained stable in humans but has undergone genetic changes in pigs. Theoretically, the changed virus is still a threat in humans to cause more serious disease. I

A new and improved diagnostic test for the 2009 H1N1 flu was approved by the Food and Drug Administration. The test is collected as a nasal swab and has been shown to be very accurate making the test very practical for the Emergency Room setting.

Distracted Driving continues to be considered a national epidemic. In 2008 more than 6,000 people died and many more were seriously injured because of distracted driving. Because no text or call is worth losing a life, physicians across the nation are being challenged to make people, particularly teenagers, aware of the danger of distracted driving and to make this advice a part of routine healthcare of patients.

In its seventh annual report of Protecting the Public's Health from Diseases, Disasters, and Bioterrorism, the Robert Wood Johnson Foundation found serious gaps in the nation's ability to respond to public health emergencies such as the H1N1 pandemic. State-by-state scores were based on 10 key indicators to assess health emergency preparedness capabilities. Nearly two thirds of states scored seven or less and eight states, AK, DE, NY, NC, ND, OK, TX, and VT, scored highest at a nine of ten indicators. Kentucky scored an eight, which is next to the highest ranking.



Scientific Assembly - September 28-October 1, 2010

Excitement is growing with the approach of this year's [Scientific Assembly](#), September 28 - October 1, in spectacular Las Vegas. Beat the rush and reserve the classes that you want, today!

Our program will include over 300 hours of world-class education, more than 300 industry-leading companies in our exhibit program, and many social events to enjoy with your colleagues. Join us and see for yourself why *Scientific Assembly* is the best in emergency medicine education!



Emergency Medicine Foundation Announces Emphasis Area in 2011-12 Grant Funding

The Emergency Medicine Foundation (EMF) is pleased to announce an area of special emphasis for its fully funded grant categories in the 2011-2012 grant cycle. To better improve emergency patient care, illustrate value in emergency medicine research, and assist the practice of emergency physicians in a changing health care environment, the EMF Board of Trustees is emphasizing innovative health services and health policy research.

EMF has been committed to supporting emergency medicine research by helping young investigators. Grants currently fully funded by EMF are the EMF Health Policy Grant (\$50,000), the EMF Fellowship (\$150,000 over two years), and the EMF Career Development Grant (\$50,000). For this grant cycle, EMF encourages applications with a focus on health services research, including but not limited to, health policy, practice, medical liability, regionalization, patient safety, and hospital utilization. However, it is important to note that EMF welcomes all applications, including research that is not health services-based.

“The Emergency Medicine Foundation has committed to supporting actionable research that directly impacts the care of our patients,” said EMF Board Chair Alexander Rosenau, DO, FACEP . “EMF will continue to underwrite a wide variety of research. The EMF Board of Trustees believes that this new era in health care reform is not only momentous, but pivotal. It demands serious investigation by the best that emergency medicine researchers have to offer in health services and health policy research.”

The Emergency Medicine Foundation also offers several co-sponsored grants, including:

EMF/SAEM Medical Student (\$2,400 each, two available).
EMF/EMRA Resident Research (\$5,000 each, three available).
EMF/ENAF Team Grant (\$50,000, one available).

The EMF is pleased to announce two new co-sponsored partnerships:
EMF/Medical Toxicology Foundation Resident Research (\$5,000, one available).
EMF/Emergency Medicine Patient Safety Foundation (\$10,000, one available).

Also new this year will be one directed research grant underwritten by Baxter in sub-cutaneous infusion (\$50,000, one available).

Grant applications will be available [online](#) in August 2010. Grant deadline is January 5, 2011.



About The Emergency Medicine Foundation

For more than 35 years, the Emergency Medicine Foundation has funded innovative clinical and laboratory research and continues to lead the way in emergency medicine education and research. To date, EMF has funded nearly \$10 million in grants for these purposes. Created to demonstrate and advance the distinctive specialty of emergency medicine through research and education, the Emergency Medicine Foundation was founded in 1972 as a 501(c) 3 charitable foundation. For more information, visit www.emfoundation.org.



Clinical News

CME Article on Reversal of Anticoagulation Now Available

Originally printed in ACEP News, the "Focus On" series of articles brings the latest literature and best practices to help the busy emergency physician provide the best care possible.

This issue's topic, Reversal of Anticoagulation, will help the physician understand the indications for reversal of warfarin, identify the side effects of protamine in heparin reversal, and recognize the advantages and disadvantages of fresh frozen plasma (FFP) vs. prothrombin complex concentrates (PCC) in the treatment of warfarin reversal.

[Read the article online and then take the CME quiz.](#)

Perspective EHR Report: What's Missing From the Meaningful Use Criteria

Since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in February of 2009, there has been a tremendous amount of discussion about the idea of "meaningful use." And now that the full set of rules for meaningful use is available, it might surprise some to know what has actually been excluded from the criteria.

The first and most fascinating exclusion is any requirement for encounter note generation. The criteria specifically state that it will not be necessary for providers to document their encounter notes using the EHR. In other words, while most EHR products emphasize electronic note generation, the authors feel this does not provide a significant benefit over handwritten charting in meeting the goals of HITECH.

[Read the full article](#)

Diffuse Nature of MRSA Abscesses Contribute to High Treatment Failures

Methicillin-resistant Staphylococcus aureus abscesses, when compared by ultrasound with those caused by other pathogens, are smaller and more likely to lack a defined edge. They are also more likely to have edema in surrounding tissue planes as well as pus divided into multiple pockets within the abscess, according to an abscess ultrasound study presented at the Society for Academic Emergency Medicine's annual meeting. The characteristics could make it more likely that an abscess is caused by methicillin-resistant Staphylococcus aureus (MRSA), helping guide antibiotic selection pending culture and sensitivity reports, according to the study's author.

[Read the full article](#)



ACEP Artistic Expressions 2010 Application Instructions

ACEP Artistic Expressions provides a unique opportunity for ACEP members to share their creative side with their colleagues. The purpose of the gallery is to encourage creative expression among members and to provide an area for reflection. The ACEP Artistic Expressions gallery will be located in the exhibit hall, in the ACEP Resource Center, during the conference and will remain on display from September 28-30, 2010.

Please submit no more than two (2) pieces of art or literature for display in the gallery. A separate application must be submitted for each piece. Articles must not have been accepted for past galleries. If accepted, you must ship your artwork to ACEP headquarters no later than August 23, 2010, to be included in the shipment to the meeting. If artwork is not received by this date, you will be responsible for all mailing/shipping costs, including insurance, and delivery to the exhibit. Work must be delivered to the Convention Center on Monday, September 27, 2010.

Security will be provided for the gallery area but ACEP cannot guarantee safety of all art and creative displays. You MUST commit to the availability of your work during the entire Scientific Assembly. You are responsible for pick up of your artwork, unless you agree to donate it to EMF (see application). If you do not arrange for pick up of your artwork by the end of the exhibit, it will be discarded or donated to EMF for auction.

If you wish to display your works, please complete the [application](#) and submit this application and all required supporting materials no later than August 2, 2010 to:

American College of Emergency Physicians
Attn: Tracy Napper
P.O. Box 619911
Dallas, TX 75261-9911

Or via e-mail to tnapper@acep.org

Supporting materials for rejected submissions will not be returned so please submit copies or digital images rather than original pieces.



Physician Assistants in the ED

By: Cary Stratford PA-C DFAAPA

Since the mid-60s, physician assistants (PAs) have been practicing in emergency medicine (EM). Today, nearly 10 percent of the estimated 74,000 clinically practicing PAs work in EM. In fact, EM is the second largest specialty in which PAs practice – equal to all surgical specialties and sub-specialties combined. And, given the increase of ED volume in the past few years, the number of EMPAs is likely to only increase.

PAs practice medicine with the supervision of licensed physician and, although by law PAs are dependent practitioners, they typically exercise considerable autonomy in clinical decision-making.

The relationship between the physician and PA is one of mutual trust and reliance. The physician trusts the PA to provide physician-quality care to patients and to consult with the physician on those cases that are outside the PA's expertise or scope of practice. The PA trusts the physician to be available for supervision, provide learned advice, and accept the care of patients with serious or complex problems.

PAs in emergency medicine also serve in patient triage, and selective administrative functions as well as providing emergency care in pre-hospital situations, in ground and air transport.

PA Education

PAs are educated in intensive programs that are accredited by the Accreditation Review Commission on Education for the Physician Assistants (ARCEPA). Programs are offered at medical schools, colleges and universities, affiliated with teaching hospitals. The typical student has a bachelor's degree and four years of health care experience prior to admission. All PA programs include courses and rotations in emergency medicine.

PAs must pass a national certifying examination before they can practice. Only graduates of accredited programs may take the exam, which is developed by the National Board of Medical Examiners and administered by the National Commission on Certification of Physician Assistants (NCCPA). To maintain certification, PAs must complete 100 hours of CME every two years and take a recertification examination every six years.

The relationship between PAs and physicians begins in PA school where physicians, PAs, and others provide instruction in a curriculum following the medical school model. A physician can more effectively care for patients when working as part of a physician-PA team. The physician-PA team approach is particularly effective because of the similarities in physician and PA training, and the efficiencies created by utilizing the strengths of each professional in the clinical practice setting.

The EP's Role

The medical director of the emergency department or other emergency physician (EP) can serve as supervising physicians. And because medical practice and physician/PA practices are dynamic, specific lists of approved tasks that physicians can delegate to PAs are not practical.

A PA's scope of practice is developed by the EP-PA team and defined by state law and regulation. It's also shaped by facility policy and the education, experience, and expertise of the PA; and by the determination of the supervising physician(s) about what tasks will be delegated. Emergency physicians are given the ultimate control over delegation, and can tailor the PAs practice to the department's needs.

In a comprehensive 2009 ACEP/SEMPA commissioned survey, completed by the NCCPA more than 68% of PAs in emergency medicine identify themselves as working in the main ED, and less than 20% identify practice limited to Fast Track. While PAs provide all the evaluation and procedures typically associated with Fast Track acuity, this survey demonstrates that many are engaged in advanced procedures and higher acuity patients.

More than 70% of EMPAs indicated that they do multi-layer wound closures, major joint dislocation reductions and arthrocentesis; more than 50% indicated that procedural sedation, slit lamp examination, and LP were among the tasks assigned to them. Just under half are experienced in Rapid Sequence Intubation.

The survey shows that 75% of EMPAs work in departments with 100% attending EP coverage; the remaining 25% work in remote or rural systems or outside the ED, with varying levels of EP presence. In these situations the same rules and regulations on PA supervision apply.

SEMPA

The Society of Emergency Medicine Physician Assistants (SEMPA) serves as the exclusive professional organization representing PAs in emergency medicine. SEMPA's mission is to promote and support the professional, clinical and personal development of physician assistants involved with emergency medicine and to advance the practice of emergency medicine.

As of January 1, 2010, ACEP began providing association management services to SEMPA, working on the goals and objectives that matter most to emergency medicine physician assistants – improving patient care, enhancing practice environments and contributing to the solution on workforce issues.

“The members of SEMPA and ACEP are dedicated to providing the highest quality emergency care to their patients,” says SEMPA Executive Director Michelle Parker. “We look forward to continuing our work in helping both emergency physicians and physician assistants accomplish that goal.”

For more information about PAs in emergency medicine the EP-PA team or SEMPA, visit our [website](#).



Welcome New Members

Jonathan M. Bronner
Elizabeth Dearing
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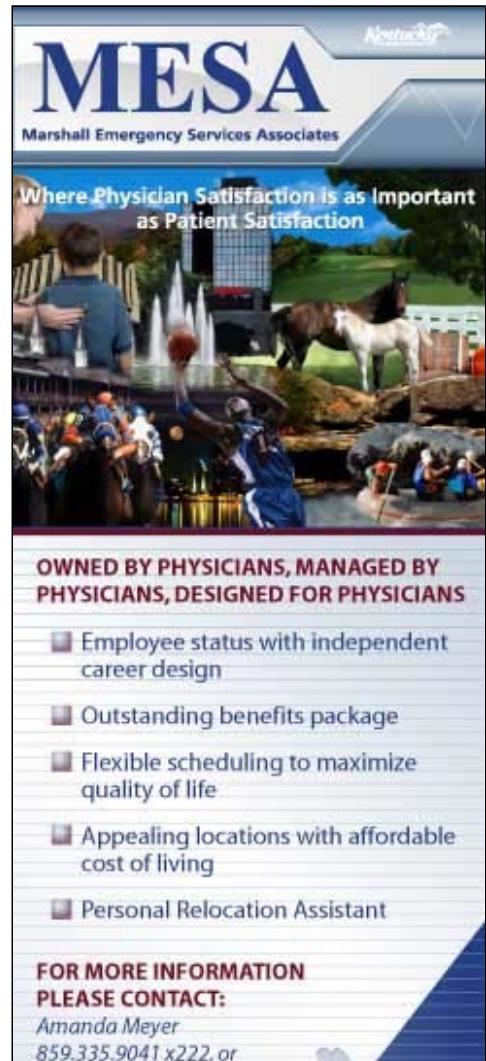


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Close monitoring of the blood pressure is required during therapy. CARDENE I.V. is contraindicated in patients with known hypersensitivity to the drug and in patients with advanced aortic stenosis. Reduction of diastolic pressure and reduced afterload may worsen rather than improve myocardial oxygen balance. Caution is advised when administering CARDENE I.V. to patients with impaired renal or hepatic function, in combination with a beta-blocker in patients with congestive heart failure, or portal hypertension. Observe caution in patients with significant left ventricular dysfunction due to possible negative inotropic effect. CARDENE I.V. gives no protection against the dangers of abrupt beta-blocker withdrawal; beta-blocker dosage should be gradually reduced. Levels of cyclosporine should be closely monitored during therapy. The most common side effects of CARDENE I.V. are headache (14.6%), hypotension (5.6%), nausea/vomiting (4.9%), and tachycardia (3.5%). Less frequent adverse effects, in each case occurring at 1.4%, include ECG abnormalities, postural hypotension, ventricular extrasystoles, injection-site reaction, dizziness, sweating and polyuria.

Please see adjacent page for brief summary of prescribing information.

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(nicardipine hydrochloride)

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Brief Summary of Prescribing Information

Cardene I.V. Premixed Injection in 4.8% Dextrose
20 mg in 200 mL (0.1 mg/mL)

Each mL contains 0.1 mg nicardipine hydrochloride, 48 mg dextrose hydrox, USP, 0.0192 mg citric acid, anhydrous, USP, and 1.92 mg sorbitol, NF. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH to 3.7 to 4.7.

Cardene I.V. Premixed Injection in 0.86% Sodium Chloride
20 mg in 200 mL (0.1 mg/mL)

Each mL contains 0.1 mg nicardipine hydrochloride, 8.6 mg sodium chloride, USP, 0.0192 mg citric acid, anhydrous, USP, and 1.92 mg sorbitol, NF. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH to 3.7 to 4.7.

Cardene I.V. Premixed Injection in 9% Dextrose
40 mg in 200 mL (0.2 mg/mL)

Each mL contains 0.2 mg nicardipine hydrochloride, 50 mg dextrose hydrox, USP, and 0.0384 mg citric acid, anhydrous, USP. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH to 3.7 to 4.7.

Cardene I.V. Premixed Injection in 0.83% Sodium Chloride
40 mg in 200 mL (0.2 mg/mL)

Each mL contains 0.2 mg nicardipine hydrochloride, 8.3 mg sodium chloride, USP, 0.0384 mg citric acid, anhydrous, USP, and 3.84 mg sorbitol, NF. Hydrochloric acid and/or sodium hydroxide may have been added to adjust pH to 3.7 to 4.7.

INDICATION AND USAGE: For the short-term treatment of hypertension when oral therapy is not feasible or desirable. For prolonged control of blood pressure, patients should be transferred to oral medication as soon as their clinical condition permits.

CONTRAINDICATIONS: Cardene I.V. is contraindicated in patients with known hypersensitivity. Cardene I.V. is also contraindicated in patients with advanced aortic stenosis because part of the effect of Cardene I.V. is secondary to reduced afterload. Reduction of diastolic pressure in these patients may worsen rather than improve myocardial oxygen balance.

WARNINGS: BETA-BLOCKER WITHDRAWAL: Nicardipine is not a beta-blocker and provides no protection against the dangers of abrupt beta-blocker withdrawal; any such withdrawal should be by gradual reduction of dose of beta-blocker.

RAPID DECREASES IN BLOOD PRESSURE: No clinical events have been reported suggestive of a too rapid decrease in blood pressure with Cardene I.V. However, as with any antihypertensive agent, blood pressure lowering should be accomplished over as long a time as is comfortable with patient's clinical status.

USE IN PATIENTS WITH ANGINA: Induction or exacerbation of angina has been seen in less than 1% of coronary artery disease patients treated with Cardene I.V. Increased frequency, duration, or severity of angina has been seen with chronic oral Cardene therapy.

USE IN PATIENTS WITH CONGESTIVE HEART FAILURE: Cardene I.V. reduced afterload without impairing myocardial contractility in preliminary hemodynamic studies of CHF patients; however, in vitro and in some patients, a negative inotropic effect has been observed. Exercise caution when using Cardene I.V., particularly in combination with a beta-blocker, in patients with CHF or significant left ventricular dysfunction.

USE IN PATIENTS WITH PNEUMOTHORAX: Limited clinical experience exists in these patients; therefore, exercise caution when administering Cardene I.V.

PERIPHERAL VEIN IRRITATION SITE: To minimize the risk of peripheral vein irritation, it is recommended that the site of infusion of Cardene I.V. be changed every 12 hours.

PRECAUTIONS: GENERAL: Blood Pressure: Cardene I.V. decreases peripheral resistance; monitoring of blood pressure during administration is required. Cardene I.V., like other calcium channel blockers, may occasionally produce symptomatic hypotension. Caution is advised to avoid systemic hypotension when administering the drug to patients who have sustained an acute cerebral infarction or hemorrhage.

Use in Patients with Impaired Hepatic Function: Nicardipine is metabolized in the liver; exercise caution in patients with impaired liver function or reduced hepatic blood flow; consider use of lower dosages. Nicardipine administered intravenously has been reported to increase hepatic venous pressure gradient by 4 mmHg in cirrhotic patients at high doses (5 mg/20 min). Use Cardene I.V. with caution in patients with portal hypertension.

Use in Patients with Impaired Renal Function: When Cardene I.V. was given to mild to moderate hypertensive patients with moderate renal impairment, a significantly lower systemic clearance and higher AUC was observed. These results are consistent with those seen after oral administration of nicardipine. Careful dose titration is advised when treating renally impaired patients.

DRUG INTERACTIONS: Since Cardene I.V. may be administered to patients already being treated with other medications, including other antihypertensive agents, careful monitoring of these patients is necessary to detect and promptly treat any undesired effects from concomitant administration.

Beta-Blockers: In most patients, Cardene I.V. can safely be used with beta-blockers. However, exercise caution when using this combination in CHF patients (see WARNINGS).

Cimetidine: Cimetidine has been shown to increase nicardipine plasma concentrations following Cardene capsule administration; carefully monitor concomitant use. Data with other histamine-2 antagonists are not available.

Digoxin: Studies have shown that Cardene capsules usually do not alter digoxin plasma concentrations; however, as a precaution, evaluate digoxin levels when initiating concomitant Cardene I.V. therapy.

Fentanyl anesthesia: Hypotension has been reported during fentanyl anesthesia with concomitant use of a beta-blocker and a calcium channel blocker. Even though such interactions were not seen during clinical studies with Cardene I.V. (nicardipine hydrochloride), an increased volume of circulating fluids might be required if such an interaction were to occur.

Cyclosporin: Concomitant use of Cardene capsules and cyclosporin results in elevated plasma cyclosporin levels. Monitor cyclosporin plasma levels closely and reduce its dose accordingly.

In vitro interaction: The plasma protein binding of nicardipine was not altered when therapeutic concentrations of furosemide, propranolol, digoxin, diltiazem, verapamil, quinidine, or naproxen were added to human plasma in vitro.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Rats treated with nicardipine in the diet (at doses of 0, 15, or 45 mg/kg/day) for two years showed a dose-dependent increase in thyroid hyperplasia and neoplasia (follicular adenoma/carcinoma). One- and three-month rat studies have suggested that these results are linked to a nicardipine-induced reduction in plasma thyroxine (T4) levels, with resultant increase in plasma levels of thyroid stimulating hormone (TSH). Chronic elevation of TSH is known to cause hyperstimulation of the thyroid. In rats on an iodine deficient diet, nicardipine administration for one month was associated with thyroid hyperplasia that was prevented by T4 supplementation. Mice treated with nicardipine in the diet (at concentrations calculated to provide daily dosage levels of up to 100 mg/kg/day) for up to 18 months showed no evidence of neoplasia of any tissue and no evidence of thyroid changes. There was no evidence of thyroid pathology in dogs treated with up to 25 mg nicardipine/kg/day for one year and no evidence of effects of nicardipine on thyroid function (plasma T4 and TSH) in man. There was no evidence of a mutagenic potential in genotoxicity tests conducted in microbes, mice and hamsters. No fertility impairment was seen in male or female rats administered oral nicardipine doses as high as 100 mg/kg/day (50 times the 40 mg TD maximum recommended human dose [MRHD]) in man, assuming a patient weight of 60 kg.

PREGNANCY CATEGORY C: Cardene I.V. administered at doses up to 5 mg/kg/day and up to 0.5 mg/kg/day to pregnant rats and rabbits, respectively, produced no embryotoxicity or teratogenicity. Embryotoxicity, but not teratogenicity, was seen at 10 mg/kg/day in rats and at 1 mg/kg/day in rabbits. Nicardipine was embryotoxic at oral doses of 150 mg/kg/day, given during organogenesis, to pregnant white rabbits but not at 50 mg/kg/day (25 times MRHD). No adverse effects on the fetus were observed when albino rabbits were treated, during organogenesis, with up to 100 mg/kg/day of nicardipine. Pregnant rats receiving oral doses up to 100 mg/kg/day (50 times MRHD) showed no evidence of embryofetotoxicity or teratogenicity. However, dystocia and reductions in

birth weights, neonatal survival, and neonatal weight gain were noted. There are no adequate and well-controlled studies in pregnant women. Cardene I.V. should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

NURSING MOTHERS: Studies in rats have shown significant concentrations of nicardipine in maternal milk. Therefore, use in nursing mothers is not recommended.

PEDIATRIC USE: Safety and efficacy in patients under the age of 18 have not been established.

USE IN THE ELDERLY: In clinical studies, no significant difference was observed in the antihypertensive effect of Cardene I.V. in patients ≥65 years compared to other adult patients.

Clinical studies of nicardipine did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE EXPERIENCES: 244 patients participated in two multicenter double-blind, placebo-controlled trials of Cardene I.V. Adverse effects were generally not serious and most were expected effects of vasodilation. Some adverse effects required dosage adjustments. Therapy was discontinued in approximately 12% of patients due mainly to hypotension, headache, and tachycardia. The following numbers represent percentage of patients with adverse experiences during the double-blind portion of controlled trials with Cardene I.V. (n=144) versus Placebo (n=100), respectively.

Adverse Experience	Cardene® (n=144)	Placebo (n=100)
Body as a Whole		
Headache	14.6	2.0
Asthenia	0.7	0.0
Abdominal pain	0.7	0.0
Chest pain	0.7	0.0
Cardiovascular		
Hypotension	5.6	1.0
Tachycardia	3.5	0.0
ECG abnormality	1.4	0.0
Postural hypotension	1.4	0.0
Ventricular extrasystoles	1.4	0.0
Ectopy	0.7	0.0
Heart block	0.7	0.0
Supraventricular tachycardia	0.7	0.0
Syncope	0.7	0.0
Vasodilation	0.7	0.0
Ventricular tachycardia	0.7	0.0
Digestive		
Nausea/vomiting	4.9	1.0
Injection Site		
Injection site reaction	1.4	0.0
Injection site pain	0.7	0.0
Metabolic and Nutritional		
Hypokalemia	0.7	0.0
Nervous		
Dizziness	1.4	0.0
Hypesthesia	0.7	0.0
Intracranial hemorrhage	0.7	0.0
Paresthesia	0.7	0.0
Respiratory		
Dyspnea	0.7	0.0
Skin and Appendages		
Sweating	1.4	0.0
Urogenital		
Polynuria	1.4	0.0
Hematuria	0.7	0.0

RARE EVENTS: The following events have been reported in clinical trials or in the literature with intravenous use of nicardipine: Body as a Whole: fever, neck pain; Cardiovascular: angina pectoris, atrioventricular block, ST segment depression, inverted T wave, deep vein thrombophlebitis; Digestive: dyspepsia, hemic and lymphatic thrombocytopenia; Metabolic and Nutritional: hypophosphatemia, peripheral edema; Nervous: confusion, hysteresis; Respiratory: respiratory disorder; Special Senses: conjunctivitis, ear disorder, tinnitus; Urogenital: urinary frequency.

Sinus node dysfunction and myocardial infarction, possibly due to disease progression, have been seen in patients on chronic oral nicardipine therapy.

OVERDOSSAGE: Several overdoses with orally administered nicardipine have been reported. One adult patient allegedly ingested 600 mg of nicardipine (standard [immediate release] capsules), and another patient, 2160 mg of the sustained release formulation of nicardipine. Symptoms included marked hypotension, bradycardia, palpitations, flushing, drowsiness, confusion and slurred speech. All symptoms resolved without sequelae. An overdose occurred in a one-year-old child who ingested half of the powder in a 30 mg nicardipine standard capsule. The child remained asymptomatic. Based on results obtained in laboratory animals, lethal overdose may cause systemic hypotension, bradycardia (following initial tachycardia) and progressive atrioventricular conduction block. Reversible hepatic function abnormalities and sporadic focal hepatic necrosis were noted in some animal species receiving very large doses of nicardipine.

For treatment of overdosage, standard measures including monitoring of cardiac and respiratory functions should be implemented. The patient should be positioned so as to avoid cerebral anoxia. Frequent blood pressure determinations are essential. Vasopressors are clinically indicated for patients exhibiting profound hypotension. Intravenous calcium gluconate may help reverse the effects of calcium entry blockade.

DOSE AND ADMINISTRATION: DOSEAGE MUST BE INDIVIDUALIZED depending on severity of hypertension and patient response. Monitor blood pressure during and after the infusion; avoid too rapid or excessive reductions in systolic or diastolic blood pressure.

Cardene I.V. Premixed Injection is supplied as a single-use, ready-to-use, iso-osmotic solution for intravenous administration in a 200 mL GALAXY container with 20 mg (0.1 mg/mL) nicardipine hydrochloride in either dextrose or sodium chloride, or with 40 mg (0.2 mg/mL) nicardipine hydrochloride in either dextrose or sodium chloride. Cardene I.V. Premixed Injection should not be combined with any product in the same intravenous line or pre-filled container. Protect from light; store in carton until ready to use. Protect from freezing. Avoid excessive heat.

See package insert for full prescribing information.

For questions of a medical nature, or to report an adverse event, please call 1-877-207-5802.

Cardene® I.V. is a registered trademark of EKR Therapeutics, Inc.

Manufactured by:
Baxter Healthcare Corporation
Dewfield, IL 60015 USA

Marketed by:
EKR Therapeutics, Inc.
Bedminster, NJ 07021 USA

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Kentucky Chapter ACEP

P.O. Box 2831

Louisville, KY 40201

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