

Kentucky Chapter Update

A Newsletter for the Members of Kentucky ACEP



Spring 2010 Issue

From the President

Barbara J. Reynolds, MD, FACEP

Brave New World

Unless you have been lucky enough to have been on a deserted beach somewhere for the past two months, you are aware of the passage of the fiercely debated Healthcare Reform Law. While many people are just glad that the poisonous rhetoric is finally over, most of us realize that we are really on the threshold of a new world in healthcare. The reality is that none of us knows exactly how this new world will function. The eternal optimist in most ED physicians causes us to hope for a better world with more patients having access to primary care and an emphasis on wellness and preventative medicine. In a perfect world, we will even be able to access follow up care for our patients with specialties such as ortho, GI and neuro. We might even see people being able to have their chronic problems well managed as outpatients and not presenting to the ED in extremis because they could not obtain care for their serious symptoms.

However, with the shortage of primary care physicians, the hoped for access provided by the new law may not translate this vision of improved care to reality any time soon. If Massachusetts can serve as an example, there will be an increase in ED volumes as many previously uninsured people obtain insurance but are still unable to find a primary care doctor.

What this means for Emergency Medicine is that we are more important in the healthcare continuum than ever before. It is more important than ever before that we continue to participate in the greater house of medicine, as well as our respective hospital communities, and advocate for our specialty and our patients. It is more important than ever before that the care we deliver is patient and safety focused. It is more important than ever before that we continue to be the specialists that will take any patient, treat any problem, advocate for our patients and always do the right thing.

Regardless of whether you were for or against this law, it is here. Although most of the debate is over, our work is just beginning. As with any change, there are both challenges and opportunities and it is up to us to shape this new world in the best possible way. I know that the

Kentucky Chapter ACEP



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dedicated people who make up this specialty are more than up to the challenge and I am confident that our patients will benefit from our work.



Tell Congress To Fix The Medicare Problem For Good! **By Dr. Wes Brewer**

After all the hoopla surrounding the passage of the healthcare reform legislation dies down, we may actually be able to figure out how this bill will really our daily lives in emergency medicine. The more important considerations are two glaring omissions from the bill that will continue to complicate our everyday practice. The first major omission was the near complete failure even mention liability reform other than the provision for a few anemically funded demonstration grants for states to evaluate reform projects on a very limited basis. Admittedly, any liability reform on the federal level will be challenging to say the least.

The other problem is the continuing inability to solve the problem of the flawed Medicare Sustainable Growth Rate formula (SGR). This is problem that is the creation of Congress yet they have perpetually been unable correct their own failure. This is one of the few items in Washington that is truly bipartisan in that both political parties have been equally inept at repairing their own screw-ups.

The SGR formula was passed as a part of the Balanced Budget Act of 1997. It requires that Medicare payments to physicians be adjusted annually based on several factors (including gross domestic product) few of which are related to the cost of providing care to seniors. Shortly after passage most of the world realized it was seriously flawed but instead of instituting a real fix, each year Congress plays a game of chicken with the medical community and then usually passes a temporary reprieve to avert a payment cut. They then add the cost of avoiding a payment cut to the estimated cost of "fixing" the formula for the next year. The longer the permanent fix is delayed the greater the cost and magnitude of future cuts. While the formula could have been fixed in 2005 for an estimated \$49 billion, the estimated cost is now up to nearly \$250 billion and goes up each month that we get a temporary reprieve. How many congressmen would willingly and silently accept a 21% pay cut? They apparently don't realize that we know that these are play numbers and budgetary gimmicks but there are real consequences. If not fixed within the next five years, the cuts will approach 40%. Congress may begin work on a permanent solution after the Congressional Easter recess, so now is the time that each one of us needs to call Congress and remind them of the urgency of finding a solution to this problem now. I would urge each KACEP member to call both of our Senators and your Congressman. You might leave a message, but it is more effective to speak with their healthcare staff person. Call back periodically until something gets done. Emailing is another option, but not as effective as a phone call. If you don't already have your Senators on speed dial (and maybe we all should?) go to the ACEP website and under the advocacy tab click on "contact congress" and you will be able to find phone numbers, email addresses, address for both Washington and local offices as well as a list of legislative aides. Call now-- no excuses.



ACEP's Health Care Reform Positions: A Letter to the ACEP Council

March 15, 2010

Dear ACEP Councillor,

As you know, the American College of Emergency Physicians exists to promote quality emergency care and to advocate for emergency physicians and their patients. To that end, ACEP has a well-established process for establishing policy and developing positions on issues critical to emergency care. Traditionally, ACEP focuses on patient access to the essential community service of emergency medicine and on support of emergency physicians in their various practice environments.

In recent years, there has been an increasing focus on the need for comprehensive reform of America's health care system. With almost 50 million uninsured Americans and sharply rising costs in health care, the current system is unsustainable. There is, however, considerable disagreement and controversy over how to fix the severely challenged health care system.

In 2009, major bills passed the House of Representatives and the U.S. Senate that would, if enacted, result in comprehensive changes in the health care system. These bills are thousands of pages long, contain hundreds of provisions, and involve substantial cost. For the past year, there has been a constantly shifting landscape of proposed reforms. Currently, President Obama is making a concerted effort to get Congress to pass a comprehensive reform package with additional elements he favors. The fate of this effort is unknown at the time of this writing due to the deeply divided opinions in Congress. ACEP has not endorsed any of the bills pending before Congress.

The divisions in Congress reflect the deep divisions within the American public, where there is concern not only about specific provisions of the reform proposals, but whether the reform effort in total would in fact restrain costs, improve quality, have adequate revenue to pay for expansions in coverage, and implement appropriate changes. There are deep divisions within the larger House of Medicine and within ACEP's membership about the major aspects of the proposed health reform bills .

Over the past three years, ACEP has conducted various surveys and discussions with its officers, Board of Directors, the Council, the members of the Federal Government Affairs Committee, the State Legislative/Regulatory Committee and other key committees concerning elements of comprehensive reform. These elements have included, but are not limited to, a single payer system, health savings accounts, health information technology, community rating, guaranteed issue, benefits, deductibles, and mandates. There has been significant variability of opinion in many of these areas, but these dialogues and inputs have guided the ACEP Board in taking the positions it has taken.

In 2008, the ACEP Council adopted Substitute Resolution 24(08): "RESOLVED, That the Board of Directors derive a list of essential components to be included in any new healthcare system and create a white paper." Understandably, ACEP's members and the ACEP Council wish to know ACEP's "official" positions with regard to health care reform. To that end, please find attached an information paper designed to convey the essential components of reform that exist in ACEP's policies and positions and a brief summary of the history and/or strategy employed with regard to the current mutable health care reform debate. Also, please bear in mind that in many cases there is agreement on a principle, but not agreement on the specific mechanisms or ways in which to accomplish that principle.

In addition, ACEP does not have official positions on many of the elements being proposed for reform.

The American College of Emergency Physicians is a representative democracy, and your disagreement with any of the policies can and should be addressed in the form of a resolution to the Council, to be debated with and by your peers who represent a diversity of geography, practice environment and specialized interests. In addition, policy can be influenced by participation on committees, in sections, and in your local chapter. I encourage you to make your voice heard by contributing to the solutions. Emergency physicians are innovators and problem-solvers and I have absolute confidence that our specialty and our members have significant contributions to make in the effort to provide better health care for all Americans.

Sincerely,

Angela F. Gardner, MD, FACEP
President



Emergency Preparedness and Disaster Planning
L. Barrett Bernard, MD
Chair, Emergency Disaster and Preparedness

Spring in Kentucky means daffodils, bluegrass, horse racing, and TORNADOES. Historically compared to other states, Kentucky ranks 27 for frequency of Tornadoes, 15 for number of deaths, 13 for injuries, and 23 for cost of damages. With reports of the possibility of more storm activity than usual this spring it is a good reason to review the emergency preparedness of each of our respective healthcare facilities. As healthcare leaders, we are expected to lend objective advice about all aspects of the impact of disasters. Many resources for this information are available including <http://emergency.cdc.gov/disasters/tornadoes/prepared.asp>, <http://kyha.com>, and <http://acep.org>.

In 2007 AAA reported that 21% of fatal car crashes involving teens between ages 16-19 were the result of cell phone usage with an increase of 4% per year expected. With similar information the KY. Legislature has to be congratulated for passing the texting ban while driving. Kentucky joins 19 other states and the District of Columbia where texting is banned during driving. We should congratulate our Legislators for the passage of this positive lifesaving measure.

The H1N1 pandemic has slowed to a low baseline. Very few new cases nationwide are being reported in the last three months. The timing of peaks of this virus were unusual compared to seasonal influenza peaks so the incidence of new cases this summer and fall are unpredictable.



New CME Feature Now Available in Every Newsletter

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, **Acute Ischemic Stroke**, will help the physician identify the management steps in treating patients suspected of having AIS, understand the complex issues that determine appropriate candidates to receive thrombolysis, and understand the risks of using rTPA.

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



Clinical News

U.S. H1N1 Vaccination Patterns Show Marked State Variation

Uptake of the influenza 2009 H1N1 vaccine by the American public showed a striking state-by-state variation, ranging from a high of 39% in Rhode Island to a low of 13% in Mississippi, the U.S. Centers for Disease Control and Prevention reported April 1.

[Read the entire article](#)

MRI Helpful in the Diagnosis of Spontaneous Intracerebral Hemorrhage

MR imaging and angiography can be a valuable adjunct for the diagnosis of spontaneous intracerebral hemorrhage, with a diagnostic yield of 42% in a prospective study of 160 patients. “Early routine MRI/MRA has substantial additive clinical benefit in patients who present with spontaneous [intracerebral hemorrhage] and/or [intraventricular hemorrhage], and it does affect management in a substantial subset of patients,” Dr. Christine Wijman said at the International Stroke Conference.

[Read the entire article](#)



About The Emergency Medicine Foundation

The Emergency Medicine Foundation (EMF) is the oldest organization with the sole purpose of supporting research and education in the specialty, founded in 1972. EMF continues to fund priorities of the American College of Emergency Physicians. The purpose of the foundation is to serve as a catalyst to advance education and research in emergency medicine. To date, EMF has awarded nearly \$10 million in research awards to advance emergency medicine science and to develop emergency medicine research. For more information, please visit

www.emfoundation.org.



Going to the 2010 ACEP Leadership and Advocacy Conference?

The Emergency Medicine Foundation looks forward to honoring our major donors and Wiegstein Legacy Society members at this fun event. (By invitation only)

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**Blue Jay Consulting and the Emergency Medicine Foundation Announce
The 2010 Emergency Department Director of the Year Winner and Finalists**

Blue Jay Consulting and the Emergency Medicine Foundation announced that Dr. Rex G. Mathew of Thomas Jefferson University Hospital, in Philadelphia, PA, has been named Emergency Department Director of the Year and honored three additional finalists for the award.

“We are proud to announce that Dr. Rex Mathew was selected as the Emergency Department Director of the Year,” said Mark J. Feinberg, Managing Partner, Blue Jay Consulting. “We received numerous, very impressive nominations and are pleased to honor Dr. Mathew and the finalists for their contributions to their discipline. They labored tirelessly to improve processes, demonstrated a superior level of expertise, and worked with their team to enhance patient care. We look forward to seeing these doctors fulfill their limitless potentials as they continue to provide patients and the hospitals they serve with the utmost efficiency, clinical standards, education and community service.”

This new annual award created by Blue Jay Consulting recognizes current emergency department physician leaders who made significant impacts on improving the operations of his/her departments, resulting in improvements in the quality of patient care. The award winner and finalists were chosen from nearly 80 nominations from across the country, including some overseas, by a selection panel composed of appointees from Blue Jay Consulting and the Emergency Medicine Foundation.

The winner and finalists demonstrated significant contributions to their emergency department in the following categories: quality patient care, operational effectiveness, education, and community service. They demonstrated collaborative relationships with nursing and ancillary departments to implement and improve operational and clinical standards based on evidence-based practice. They also stood out for their abilities to create and sustain high degrees of patient satisfaction, while implementing creative and innovative strategies to address emergency department throughput.

Linda Lawrence, MD, FACEP, EMF board member, will honor the winner on April 26, 2010, at the American College of Emergency Physicians Emergency Department Director's Academy, Phase II.

This year's winner, Rex G. Mathew, MD, FACEP, is vice president of emergency medicine clinical operations at Thomas Jefferson University Hospital, a Level 1 Trauma Center in

Philadelphia. Dr. Mathew displayed his leadership abilities, combined with his clinical knowledge, to work with leaders throughout the hospital to improve care in the emergency department. He fulfills a unique roll for the department and the hospital as both an administrator and a practicing physician. Having his “feet in both doors” has enabled him to make a positive impact on his patients and fellow clinicians. In addition, Dr. Mathew was instrumental in developing many quality improvement projects including the newly accredited Thomas Jefferson Chest Pain Center.

“The emergency department director not only sets the tone and direction for the emergency department, but serves as the point person to satisfy patient’s needs and provide safe, quality care,” said EMF Chair, Alexander Rosenau, DO, FACEP. “Because the emergency department serves as the safety net for our community, emergency directors’ roles are invaluable and a service that the community needs 24/7. We are pleased to honor Dr. Mathew as he demonstrates that emergency medicine is a team sport and provides the quality care that patients come to expect.”

The two organizations applauded this year’s finalists who are listed alphabetically:

Patrick J. Crocker, DO, MS, FACEP, is the chief, of emergency medicine at Dell Children’s Medical Center of Central Texas in Austin, TX. Dr. Crocker was instrumental in working across disciplines to create the Comfort Zone Program, which addresses the comfort, anxiety and pain perception of patients. In addition, he worked closely with emergency nursing leadership to adopt high standards of professional performance and conduct.

William Dalsey, MD, MBA, FACEP, is the chairman of the department of emergency medicine at Kimball Medical Center in Lakewood, NJ. Dr. Dalsey’s collaborative approach to patient care earned Kimball Medical Center top honors for the last five years in patient satisfaction scores by Press Ganey. In addition, Dr. Dalsey and the nurse manager transformed emergency operational efficiency to reduce door-to-doctor times, as well as overall throughput while never compromising quality. His “no wait ED” was one of the first of its kind.

Paul Ernest Pepe, MD, MPH, FACEP, is the chief of emergency services at Parkland Health & Hospital System in Dallas, Texas. Dr. Pepe’s strong team philosophy stood out in his application. Both he and Jennifer Sharpe, RN, director of nursing, were recognized because they epitomize the work ethic and philosophical temperament that guaranteed the tremendously successful journey to better patient care and enhanced community service at one of them most visible emergency care centers. Dr. Pepe is an award-winning physician who serves as an inspirational mentor.



ACEP LLSA Resource Center Updated to Include 2011 Articles

The ACEP LLSA Resource Center is being updated today with new tools to help you prepare for your annual LLSA tests and maintain your ABEM certification. New today are the 11 articles on the 2011 Lifelong Learning and Self-Assessment Reading List, summaries of the articles on the 2010 list, and handouts from lectures on the 2009 list.

The ACEP [LLSA Resource Center](#) is one of the most valuable benefits of your ACEP

membership. If you've never used it, take a few minutes to do so right now. You'll find the list of all current readings (the 2008 through 2011 lists), information on the CCME-ACEP program EM:Prep, information on LLSA prep programs hosted by chapters, and links to LLSA-specific pages on the ABEM Web site. Then for ACEP members only is the really good stuff – the articles themselves – all 61 of them, which you won't find anywhere else all in one place for no extra charge. The members-only area also contains article summaries published in Critical Decisions in Emergency Medicine and the handouts from the LLSA lectures at the 2009 Scientific Assembly.

How can you get it all? Go to the [LLSA Resource Center](#). Click on the links for the information you want. If you want something in the "Resources Available to ACEP Members Only," you'll need to log on using your ACEP user name and password. If you've never done that before, just follow the instructions on the sign-in page. If you need more help, call ACEP Member Services, 800-798-1822, ext. 5.

And if you have comments, questions, or suggestions for improvement, [e-mail](#).



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Each mL contains 0.1 mg nicardipine hydrochloride, 48 mg dextrose hydroxide, 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 0.65% 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 5% Dextrose 40 mg in 200 mL (0.2 mg/mL)

Each mL contains 0.2 mg nicardipine hydrochloride, 50 mg dextrose hydroxide, 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 0.65% 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 1.92 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 compatible 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 inspiring 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 PHEOCHROMOCYTOMA: Limited clinical experience exists in these patients; therefore, exercise caution when administering Cardene I.V.

PERIPHERAL VEIN INFUSION SITE: To minimize the risk of peripheral venous 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 (3 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 prevent that 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.

Cyclosporine: Concomitant use of Cardene capsules and cyclosporine results in elevated plasma cyclosporine levels. Monitor cyclosporine 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, dipyridamide, warfarin, quinidine, or sargramin were added to human plasma in vitro.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY: Rats treated with nicardipine in the diet (at doses of 5, 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 TID 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 embryocidal 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 embryolethality 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.

Percent of Patients with Adverse Experiences
During the Double-Blind Portion of Controlled Trials

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
Extrasystoles	0.7	0.0
Heartmurmur	0.7	0.0
Hypertension	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
Hypertesthesia	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		
Polyuria	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, hyperreflexia. **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.

OVERDOSAGE: Several overdosages 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 overdosage 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 overdosage 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.

DOSEAGE 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-site, 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-mixed 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
Deerfield, IL, 60015 USA

Marketed by:
EKR Therapeutics, Inc.
Bedminster, NJ 07921 USA

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