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Today

Health-System
Edition

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A professional balancing act

I need to rearrange the weekend schedule so I can attend the party for my parents' wedding anniversary. I hope my coworkers will help out." "I can't have an active role in the pharmacy association, because I know it would be a scheduling nightmare every time I need to take off for a meeting."

These are just some of the common concerns of busy pharmacists. Between work, children, parents, and other time commitments, managing a work-life balance keeps many pharmacists awake at night. Pharmacy school prepares well-trained, clinically competent professionals but spends little time teaching how to juggle work and home commitments—a challenge that changes throughout the different stages of life. For example, new graduates who have just begun their careers may be reluctant to ask for time off for family or professional activities.

In institutional settings, these issues may seem less pressing because of greater staff availability. In reality, however, time management can become more problematic because of the necessity for 24-7 coverage and other staffing demands. To have a good work-life balance, you must determine what is important to you, know how to set goals and develop priorities, and realize that you may need to adapt your priorities to your situation.

Pharmacy professionalism

Professionalism is integral to being a pharmacist, but this term can encompass many things. Some characteristics of a professional pharmacist include high ethical standards, consistency, fairness, continual learning and self-improvement, comprehension of and action on issues facing the profession, and giving back to the profession.

When looking at your work-life balance, sometimes parts of professionalism get lost. Most pharmacists have high ethical standards that they follow each day, but what about some of the other parts of being a professional, such as understanding and acting on the issues facing the profession? It can be easy to get "tunnel vision" and only worry about what's happening at your own hospital.

Association membership

One way to counteract tunnel vision is to get involved with a national pharmacy association like APhA. Through activities sponsored by APhA, as well as other local, state, or national pharmacy associations, you can learn more about current trends in pharmacy. Knowing what is happening and how it may affect you and your patients is critical. From simply joining an associa-

tion to running for elected office, there are many paths for involvement in a pharmacy association. No matter the level of your involvement, your work life—and ultimately, patient care—will only improve through your participation.

The balancing act of professional pharmacy association membership vs. work vs. family is something that keeps many of us awake at night. You may know the benefits of pharmacy associations, but where do these benefits fall on your own personal priority scale? Belonging to a professional organization should not be seen as a professional obligation, but as something desirable, as your involvement can spur professional development and satisfaction. It's okay if your level of involvement changes based on your other priorities. Setting goals and priorities for what you hope to achieve from your membership will help you make these decisions.

Cathy and Tom Worrall, the subjects of our profile this month, are an excellent example of a pharmacist couple who have been able to balance their family, careers, and involvement in pharmacy associations. It isn't always easy to achieve that balance, and it may take you some sleepless nights to get there, but knowing that you are reaching a higher level of professionalism and taking better care of your patients can help make the insomnia worthwhile.

—Melinda C. Joyce, PharmD
Pharmacy Today Health-System
Edition Editor

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Melinda Joyce



Top tips for barcode implementation

AHRQ summarizes hospitals' experience putting barcode medication administration into practice

In a recently released report, the Agency for Healthcare Research and Quality (AHRQ) presented key findings on the implementation of medication administration technologies—specifically, barcode medication administration (BCMA) and electronic medication administration record (eMAR) technologies. The agency based its recommendations on 11 grant projects using barcode technologies; these projects are located across the country, in both urban and rural areas.

Through interviews with AHRQ-funded projects, the agency identified three main areas requiring consideration before instituting a medication administration system: the technology being implemented, the means of implementation, and the characteristics of the organization.

Technology: Interoperability is key

The technology used by an institution is paramount to the success of a BCMA system. Most AHRQ grantees preferred interoperable applications to standalone, “best-of-breed” systems. Institutions saw applications that could work with other IT interfaces as a cost-saving measure. Small and rural hospitals were especially positive about these systems, as these hospitals could not sustain the larger IT staff required for maintenance and support of a standalone system.

Grantees commented that “pilot testing facilitated a more successful implementation.” Common problems caught during pilot testing included scanners that were not compatible with all barcodes used and wristbands that could easily be lost or become unreadable.

The institutions also recommended performing pilot tests in smaller units and/or units with low-acuity cases. A related issue is the timing—simultaneous or separate implementation of BCMA and eMAR—and location—all units at once or unit-by-unit—of the technology rollout. AHRQ reported that the grantees “did not come to a consensus regarding the order in which to implement medication administration technologies,” however.

Implementation: Practice, practice, practice

Training, of course, is essential to a successful implementation. AHRQ grantees emphasized the importance of providing sufficient time for training and extending training to all relevant positions. Some institutions found it effective to integrate the training process with pilot testing. Another successful strategy was to deploy “superusers” who would receive extra training and provide peer-to-peer support for their coworkers. Most grantees also reported relying on on-site assistance from vendors.

Grantees cautioned that some manufacturers do not comply with FDA's mandate to print barcodes on all medications at the unit dose level. Additional problems can include codes that are incompatible with scanners and drugs that need to be further repackaged before administra-

tion. In all of these cases, hospitals will need a backup strategy to relabel products, either by purchasing a packaging/labeling machine for the institution or by outsourcing barcoding.

Organization: Strong culture leads to success

Because BCMA and eMAR “are not simple tools that can be easily integrated into a new environment,” grantees had to plan for a cultural change. Many grantees told the agency about significant changes to the social structure of their hospitals.

Communication between nurses and pharmacists will likely increase. The increased interdependence between the pharmacy and other departments can improve staff relationships if personnel are prepared for this change. Communication and collaboration during the planning and implementation stages can avoid turf wars between pharmacists and other hospital staff. One strategy

many hospitals used to improve collaboration was to focus on nurse champions—nursing personnel who became strong supporters of BCMA and eMAR as error-preventing tools and helped encourage staff buy-in.

Setting proper expectations for the implementation of these technologies is also helpful in preparing employees. “According to the grantees, BCMA and eMAR systems had no impact on nurses' workload, and in some projects, increased workload for pharmacy staff. Many grantees believed that BCMA and eMAR decreased nursing efficiency in the short term but had no effect over the long term,” wrote AHRQ. As a result, hospitals should not promote these technologies as time-saving tools; instead, focus on their actual benefits in reducing errors and allowing for more extensive evaluation of medication administration.

—Alex Egervary



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MTM the Worrall way

*Both pharmacists, both successful,
both leaders in the profession*

APhA Executive Vice President and CEO John Gans's "amazing vision" for the pharmacy profession and a desire to lead the profession are two major reasons that Thomas J. Worrall, PharmD, BCPS, FAPhA, Ambulatory Care Clinical Pharmacy Specialist at the Ralph H. Johnson Department of Veterans Affairs Medical Center in Charleston, SC, and Cathy L. Worrall, BSN, PharmD, BCPS, BCNSP, FAPhA, Trauma/Surgical Critical Care/Nutrition Support Clinical Pharmacy Specialist at the Medical University of South Carolina in Charleston (MUSC) Medical Center, take active leadership roles in APhA and in their profession. In a recent interview with *Pharmacy Today*, Tom explained that his motto with regard to the pharmacy profession is "Give back, lead, and positively move the profession." Cathy has a similar philosophy as her husband and noted, "It is important to be involved so that you can help shape the future of pharmacy."

The Worralls have been very involved in APhA since pharmacy school. Cathy attended her first APhA Annual Meeting as a first-year student pharmacist at the University of Florida and has been actively involved in APhA for the past 19 years. Tom has been a member of APhA since attending pharmacy school at Rutgers University. Cathy and Tom both served as President of their APhA Academy of Student Pharmacists Chapters. Cathy also served as a Regional Delegate and National Executive Committee Member-at-large. When asked how they met, the Worralls laughed and explained that mutual friends introduced them—where else, but at the APhA Annual Meeting in Dallas during their last year in pharmacy school! Tom and Cathy both served as New Practitioner Officers in the APhA Academy of Pharmacy Practice and Management (APPM) after graduation and went on to serve as section officers. Cathy is completing her final year as Member-at-large of the APhA-APPM Executive Committee.

Providing MTM in the ambulatory care environment

Tom spends the majority of his day in the VA's primary care arena taking care of patients. He remarked, "I feel blessed to be taking care of America's heroes." He sees patients in two main clinics—anticoagulation and pharmacotherapy. In the former, Tom manages patients on long-term anticoagulation therapy; in the latter, he provides medication therapy management (MTM) services to patients with diabetes, lipid disorders, chronic obstructive pulmonary disease, heart failure, and hypertension. Tom noted, "I do everything for my patients from ordering labs to prescribing medications." When he is consulted by one of the attending physicians to manage a patient, Tom is able via his scope of practice to initiate, change, or stop medications that

**"Give back, lead,
and positively move
the profession."**

are used to treat the disease states for which he is consulted. "This is not to say that the attending physicians are not accessible. They are always available when I need to run something past them," he explained. Tom noted that he has a "very positive working relationship with all of the attending physicians in his ambulatory care clinic" and that he could not ask for a more supportive medical staff.

"Serving patients in the primary care environment can be very stressful but it also comes with many rewards," Tom explained. He recounted the story of one of his favorite patients: "I met this gentleman when he was 53 years old. At that time he and his wife were worried about his health and his life expectancy. His father had died in his forties and all of his three broth-





ers had died in their fifties.” At the first visit, Tom knew that managing this patient’s cardiovascular medications was going to be a challenge; he had already had one myocardial infarction, was on a blood-thinning medication, was unable to take statin medications because of severe adverse drug reactions, and had been deemed by his cardiologist as not a candidate for future surgical interventions.

When Tom started working with the patient, his LDL cholesterol (LDL-C) was 148 mg/dL and he was taking high-dose niacin and high daily doses of colestipol (Colestid—Pfizer). The patient was suffering numerous adverse effects from the two lipid-lowering medications. Tom has been seeing the patient for 10 years now, and he described the patient’s progress: “He is now 63 years old and has lived longer than any of his first-degree male relatives. His LDL-C ranges from 60–80 mg/dL, and he is being managed on low-dose rosuvastatin 5 mg [Crestor—AstraZeneca] and ezetimibe 5 mg [Zetia—Merck/Schering-Plough] each day. I know that this gentleman and his wife appreciate the time and the care that my pharmacy residents and I have given to him. This year for Christmas, his wife sent my family a tin of homemade goodies to enjoy as appreciation.”

When not in clinic, Tom is frequently teaching and mentoring student pharmacists and pharmacy residents. He also serves as Assistant Clinical Professor in the Department of Clinical Pharmacy and Outcomes Sciences for the South Carolina College of Pharmacy (SCCP) MUSC campus in Charleston. He enjoys medical writing; he has been a contributor to the APhA Federal Pharmacist Update e-newsletter since 2004.

Providing MTM to surgical-trauma patients

Cathy spends the majority of her time at MUSC Medical Center in the fast-paced surgical trauma ICU (STICU). Unlike many critical care clinical pharmacy specialists, she follows her patients throughout their hospital stay, from admission to the ICU to discharge from the floor. “I work with two surgical teams—one that manages the ICU patients and one that manages the floor patients. I am the only multidisciplinary team member who manages patients on both services, which provides continuity of care for our patients,” she explained. Cathy performs rounds first thing in the morning with the STICU team and later in the morning or early afternoon with the surgical trauma floor team. The census for her ICU and floor services varies depending on the time of year, with the summer months being the most hectic. Cathy explained, “The STICU has a 16-bed capacity, while the trauma floor service has a 21-bed capacity. During the summer months, we often exceed capacity and have patients all over the hospital.”

Cathy’s patient population includes victims of motor vehicle crashes, gunshot wounds, stab wounds, and other types of blunt and penetrating trauma. The trauma surgeons she works with also perform general surgeries, and she manages these patients as well. Cathy explained, “It is my job to manage all of the pharmacotherapy needs of these patients. I ensure that medication reconciliations are completed, round with my teams, and recommend ways to optimize drug therapies and laboratory tests to monitor for efficacy and toxicity and provide discharge counseling. I work closely with the clinical dietitians to ensure optimal nutrition therapy for my patients, including both enteral

and parenteral nutrition.” Cathy is board certified in both pharmacotherapy and nutrition support. When asked specifically about MTM, Cathy laughed and explained, “Doing MTM is my job! Most hospital phar-

macists have been doing MTM for years, long before the term MTM was coined.” Cathy noted how much the surgeons she works with rely on clinical pharmacists to manage drug therapies: “I have always enjoyed working with surgeons because they value my expertise and appreciate the services I provide to enhance patient care. They really rely on me to ensure that drug therapy management is optimized for their patients.”

When Cathy leaves the hospital, her duties as a pharmacist for that day are not necessarily over. She wears a pager 24/7 so she is available for her teams, if needed. “They only call me after hours if they really need something. We have a clinical pharmacy on-call service that can manage most drug therapy questions after hours and on weekends,” she told *Today*.

Although Cathy is employed by MUSC Medical Center, she also serves as Associate Clinical Professor in the Department of Clinical Pharmacy and Outcomes Sciences for the SCCP MUSC campus. Cathy precepts postgraduate year (PGY) 1 and PGY2 pharmacy residents and student pharmacists most months of the year. She said, “I really enjoy the students and residents. I think it is important to take students and residents on rotation because it allows us as clinicians to give back to our profession.”

Cathy enjoys clinical research in her areas of interest, which include stress-induced hyperglycemia, alcohol withdrawal, nutrition, and infectious diseases, as well as teaching at the College of Pharmacy and the College of Health Professions. She also serves as faculty advisor for the Phi Lambda Sigma Leadership Society on the SCCP MUSC campus.

Life away from the hospital

Things do not slow down when the Worralls leave the hospital. Their three children—9-year-old identical twin boys and an 11-year-old daughter—keep them very busy. Cathy explained, “All the kids are involved in sports and church activities, so we have a busy schedule most evenings and weekends. I’m a full-time pharmacist and part-time chauffeur!”

Tom enjoys sports and is currently coaching his twins’ basketball team. When Habitat for Humanity houses are being built in his area, he can frequently be seen working on Saturdays at the home site. Cathy enjoys music and participates in choir and handbells at church. As a family, the Worralls enjoy Southeastern Conference college football and were especially happy when their team, the Florida Gators, recently won the Bowl Championship Series National Championship Game versus Oklahoma.

The Worralls have served APhA in many capacities over the years. They encourage all pharmacists to become involved in APhA, noting that “APhA is the organization that represents all pharmacists, not just special segments or interest groups.”

—Ellen Whipple Guthrie, PharmD
Contributing writer

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Please see next page for brief summary of prescribing information.

References: 1. Ruble J. Impact safety, efficiency, and the bottom line with premixed IV products. Pharm Purchasing Prod. February 2008. <http://www.pppmag.com>. Accessed August 28, 2008.

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Brief Summary of Prescribing Information

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 hydrous, 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: 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 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 PHENOCROMOCYTOMA: 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: Because 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 mm Hg 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.

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, dipyrindamole, warfarin, 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 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 due to a nicardipine-induced reduction in plasma thyroxine (T₄) levels, with resultant increase in plasma levels of thyroid stimulating hormone (TSH). 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 nicardipine-induced thyroid effects in dogs (treated with nicardipine at doses up to 25 mg/kg/day for one year) or in man. Nicardipine did not display 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: There are no adequate and well-controlled studies in pregnant women; Cardene® I.V. should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. 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® 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.

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 approx. 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
Hemopericardium	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
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		
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, hypertension. **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 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 overdose, 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.

DOSAGE AND ADMINISTRATION: DOSAGE 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 available as a single-use, ready-to-use, iso-osmotic solution for intravenous administration in a 200 mL GALAXY container with 40 mg (0.2 mg/mL) nicardipine hydrochloride in either dextrose or sodium chloride. No further dilution is required. Cardene® I.V. premixed injection should not be combined with any product in the same intravenous line or premixed container. Protect from light until ready to use.

See package insert for full prescribing information.

To report an adverse event or for questions of a medical nature, please call 1-877-207-5002

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

Manufactured by:
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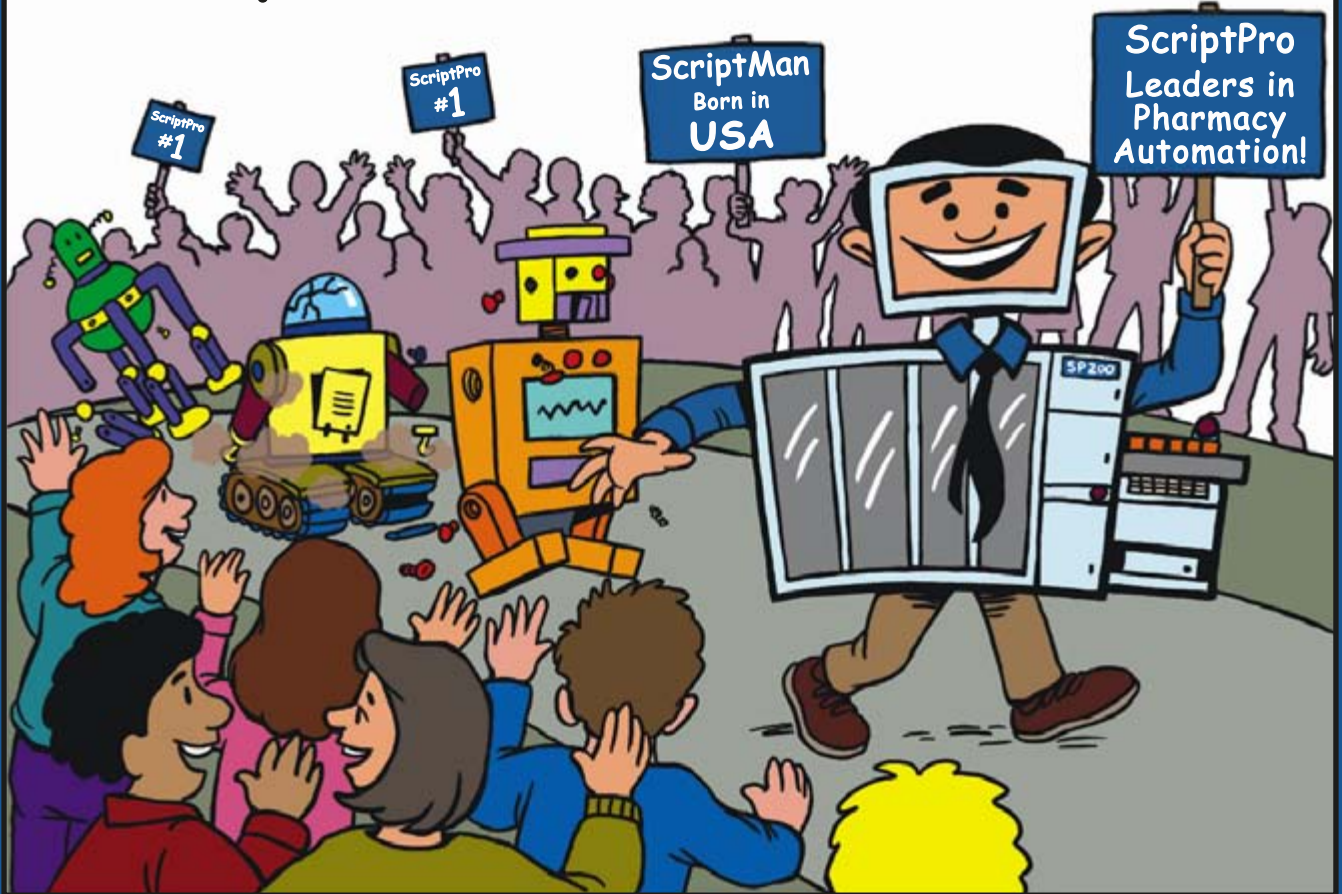
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