

# Your Role in HR Management

## Chapter FastFACTS

- 1. Understanding human resources management (HRM) will save you time and money.**
- 2. Even if your office manager handles human resources (HR), you direct it through your demeanor and decisions.**
- 3. Knowing whether your responses to personnel issues pass the HR litmus test can help avoid costly HR problems and breakdowns in customer service.**
- 4. Current staff can help with certain HR tasks.**
- 5. Many HR issues and their solutions are universal.**

**D**o your staff members complain about each other behind the scenes or tend to point fingers when a problem arises? Those are among the many HR-related issues that can have an impact not only on office morale but ultimately on your patients' experiences of care. Even if your office manager handles most HR issues, you're probably involved in HRM because you take the lead or make critical decisions on complex, sensitive HR issues. Understanding HRM better and re-evaluating your systems will save you stress, money, and time while extending the same care you give your patients to those who help you care for them.

### What is HRM?

HRM is a strategic and coherent approach to managing an organization's most valued assets—its people. Specifically,

**7 out of 10 patients**  
*with untreated hypertension present with an*  
***overactive RAAS***<sup>1,2</sup>

## IN HYPERTENSION

VALTURNA offers both superior BP efficacy and more comprehensive RAAS inhibition than valsartan<sup>3</sup>

# A SMART VALTURNATIVE



### Indication

VALTURNA is indicated for the treatment of hypertension in adults.

VALTURNA may be substituted for the titrated components. VALTURNA may be used in patients whose blood pressure is not adequately controlled on aliskiren or any ARB monotherapy and as initial therapy in patients who are likely to need multiple medications to achieve their blood pressure goals.

The choice of VALTURNA as initial therapy should be based on an assessment of potential benefits and risks. The decision to use a combination as initial therapy should be individualized and should be shaped by considerations such as baseline blood pressure, target goal, and the incremental likelihood of achieving goal with a combination product compared to monotherapy.

### Important Safety Information

**WARNING: AVOID USE IN PREGNANCY:** When pregnancy is detected, discontinue VALTURNA as soon as possible. When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin-aldosterone system (RAAS) can cause injury and even death to the developing fetus. [See *Warnings and Precautions* (5.1)]

**Angioedema:** Angioedema of the face, extremities, lips, tongue, glottis, and/or larynx has been reported in patients treated with aliskiren and has necessitated hospitalization and intubation. This may occur at any time during treatment and has occurred in patients with and without a history of angioedema with ACE inhibitors (ACEIs) or angiotensin receptor antagonists. Discontinue aliskiren immediately in patients who develop angioedema, and provide appropriate therapy and monitoring until signs and symptoms resolve. Aliskiren should not be readministered.

**Hypotension:** In clinical trials, an excessive fall in blood pressure (hypotension) was seen rarely (<0.5%) in patients with uncomplicated hypertension treated with VALTURNA. Initiate therapy cautiously in patients with heart failure or recent myocardial infarction (MI) and in patients undergoing surgery or dialysis.

**Volume- and/or Salt-depletion:** Volume- and/or salt-depletion should be corrected in patients prior to administering VALTURNA or symptomatic hypotension may occur. Patients taking VALTURNA should be observed for clinical signs of fluid or electrolyte imbalance.

**Renal Considerations:** Care should be used when dosing VALTURNA in patients with severe renal impairment. As a consequence of inhibiting the RAAS, changes in renal function may be observed in susceptible individuals (eg, patients with renal artery stenosis or severe heart failure). Patients with severe renal impairment were excluded from clinical trials with VALTURNA in hypertension.

In studies of ACEIs in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen have been reported. There has been no long-term use of valsartan in patients with unilateral or bilateral renal artery stenosis, but an effect similar to that seen with ACEIs should be anticipated.

In patients with severe heart failure whose renal function may depend on the activity of the RAAS, treatment with ACEIs and angiotensin receptor antagonists has been associated with oliguria or progressive azotemia and (rarely) with acute renal failure or death. Similar outcomes have been reported with valsartan.

- Greater SBP reductions vs valsartan
- More comprehensive RAAS inhibition than an ARB
- Established safety and tolerability
- Single-tablet dosing
- \$15 co-pay available for most patients\*

The clinical implications of differences in effect on RAAS components are not known.

\*Valid for those patients with private insurance only.

Not valid for patients whose prescription is paid for in part or in full under Medicare, Medicaid or any other federal or state program, self-paying patients (those without private insurance), or for residents of MA. Limitations apply. This card is the property of Novartis and must be returned upon request.

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Patient is responsible for reporting receipt of program rewards to any private insurer that pays for or reimburses any part of the prescriptions filled with this program.

This offer will expire on 12/31/2010.

To learn more about Valturna, talk to your Novartis sales representative.

## Important Safety Information (cont'd)

**Hepatic Considerations:** As a majority of valsartan is eliminated in the bile, valsartan should be used with care in patients with mild-to-moderate hepatic impairment, including patients with biliary obstructive disorders, because of lower valsartan clearance.

**Patients With CHF and Post-MI:** Include assessment of renal function when evaluating patients with heart failure or post-MI. Dosage reduction and/or discontinuation of a diuretic and/or valsartan may be required.

**Hyperkalemia:** In short-term controlled trials of VALTURNA, the incidence of hyperkalemia ( $K^+ >5.5$  mEq/L) was about 1%-2% higher than with corresponding monotherapies or placebo.

**Electrolyte Imbalance:** Periodic determinations of serum electrolytes to detect possible electrolyte imbalances is advised, particularly in patients at risk for hyperkalemia such as those with renal impairment.

**Cyclosporine:** It is not recommended to prescribe VALTURNA for patients who also take cyclosporine.

**Furosemide:** When aliskiren was coadministered with furosemide, the AUC and  $C_{max}$  of furosemide were reduced by about 30% and 50%, respectively. Patients receiving furosemide could find its effect diminished after starting aliskiren.

**Common AEs:** The most common adverse events (AEs) that occurred more frequently with VALTURNA than placebo were fatigue (2.6% vs 1.4%), nasopharyngitis (2.6% vs 2.2%), diarrhea (1.4% vs 0.9%), upper respiratory tract infection (1.4% vs 1.1%), urinary tract infection (1.4% vs 0.6%), influenza (1.1% vs 0.2%), and vertigo (1.1% vs 0.3%).

Please see Brief Summary of Prescribing Information, including Boxed WARNING, on following pages.

**References:** 1. Blumenfeld JD, Laragh JH. Renin system analysis: a rational method for the diagnosis and treatment of the individual patient with hypertension. *Am J Hypertens.* 1998;11(7): 894-896. 2. Alderman MH, Cohen HW, Sealey JE, Laragh JH. Plasma renin activity levels in hypertensive persons: their wide range and lack of suppression in diabetic and in most elderly patients. *Am J Hypertens.* 2004;17(1):1-7. 3. Valturna [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2010.



150/160 • 300/320 mg

*A smart option in BP lowering*



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East Hanover, New Jersey 07936

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C-VAT-100016

# Valturna *(aliskiren and valsartan, USP) Tablets*

Initial U.S. Approval: 2009

**BRIEF SUMMARY:** Please see package insert for full prescribing information.

## **WARNING: AVOID USE IN PREGNANCY**

When pregnancy is detected, discontinue Valturna as soon as possible. When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin-aldosterone system can cause injury and death to the developing fetus. [See *Warnings and Precautions (5.1)*].

## **1 INDICATIONS AND USAGE**

Valturna is indicated for the treatment of hypertension.

### Add-on Therapy

A patient whose blood pressure is not adequately controlled with aliskiren alone or valsartan (or another angiotensin receptor blocker) alone may be switched to combination therapy with Valturna.

### Replacement Therapy

Valturna may be substituted for the titrated components.

### Initial Therapy

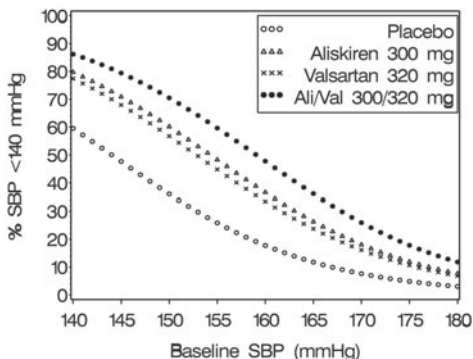
Valturna may be used as initial therapy in patients who are likely to need multiple drugs to achieve their blood pressure goals.

The choice of Valturna as initial therapy should be based on an assessment of potential benefits and risks.

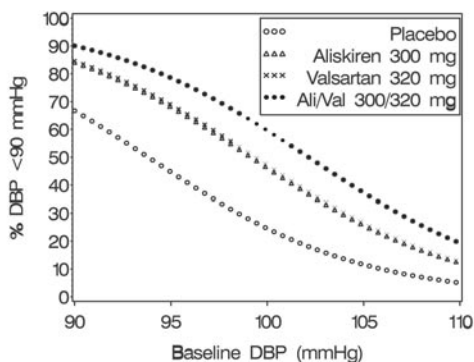
Patients with Stage 2 hypertension are at a relatively high risk for cardiovascular events (such as strokes, heart attacks, and heart failure), kidney failure, and vision problems, so prompt treatment is clinically relevant. The decision to use a combination as initial therapy should be individualized and should be shaped by considerations such as baseline blood pressure, the target goal, and the incremental likelihood of achieving goal with a combination compared to monotherapy. Individual blood pressure goals may vary based upon the patient's risk.

Data from the high-dose multifactorial study [see *Clinical Studies (14) in the full prescribing information*] provide estimates of the probability of reaching a target blood pressure with Valturna compared to aliskiren or valsartan monotherapy. The figures below provide estimates of the likelihood of achieving systolic or diastolic blood pressure control with Valturna 300/320 mg, based upon baseline systolic or diastolic blood pressure. The curve of each treatment group was estimated by logistic regression modeling. The estimated likelihood at the right tail of each curve is less reliable because of a small number of subjects with high baseline blood pressures.

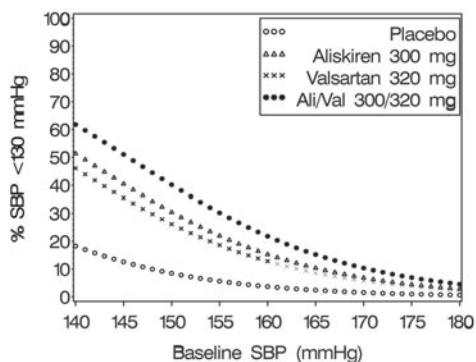
**Figure 1: Probability of Achieving Systolic Blood Pressure (SBP) <140 mmHg in Patients at Endpoint**



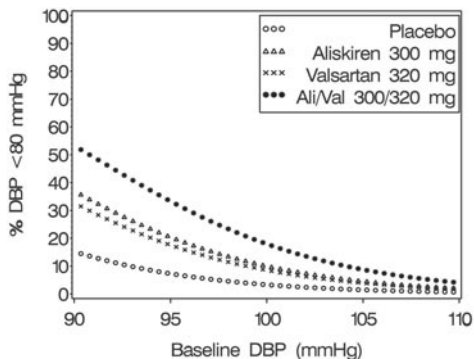
**Figure 2: Probability of Achieving Diastolic Blood Pressure (DBP) <90 mmHg in Patients at Endpoint**



**Figure 3: Probability of Achieving Systolic Blood Pressure (SBP) <130 mmHg in Patients at Endpoint**



**Figure 4: Probability of Achieving Diastolic Blood Pressure (DBP) <80 mmHg in Patients at Endpoint**



At all levels of baseline blood pressure, the probability of achieving any given diastolic or systolic goal is greater with the combination than for either monotherapy. For example, the mean baseline SBP/DBP for patients participating in this multifactorial study was 154/100 mmHg. A patient with a baseline blood pressure of 154/100 mmHg has about a 51% likelihood of achieving a goal of <140 mmHg (systolic) and 46% likelihood of achieving <90 mmHg (diastolic) on aliskiren alone, and the likelihood of achieving these goals on valsartan alone is about 47% (systolic) and 47% (diastolic). The likelihood of achieving these goals on Valtorna rises to about 62% (systolic) and 60% (diastolic). The likelihood of achieving these goals on placebo is about 28% (systolic) and 25% (diastolic) [see *Dosage and Administration (2) and Clinical Studies (14) in the full prescribing information*].

#### **4 CONTRAINDICATIONS**

None.

#### **5 WARNINGS AND PRECAUTIONS**

##### **5.1 Fetal/Neonatal Morbidity and Mortality**

Valtorna can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if a patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus.

Drugs that act directly on the renin-angiotensin-aldosterone system can cause fetal and neonatal morbidity and death when administered to pregnant women. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus [see *Use in Specific Populations (8.1)*]. In several dozen published cases, use of ACE inhibitors during the second and third trimesters of pregnancy was associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. In addition, first trimester use of ACE inhibitors has been associated with birth defects in retrospective data.

##### **5.2 Head and Neck Angioedema**

###### *Aliskiren*

Angioedema of the face, extremities, lips, tongue, glottis and/or larynx has been reported in patients treated with aliskiren and has necessitated hospitalization and intubation. This may occur at any time during treatment and has occurred in patients with and without a history of angioedema with ACE inhibitors or angiotensin receptor antagonists. If angioedema involves the throat, tongue, glottis or larynx, or if the patient has a history of upper respiratory surgery, airway obstruction may occur and be fatal. Patients who experience these effects, even without respiratory distress, require prolonged observation since treatment with antihistamines and corticosteroids may not be sufficient to prevent respiratory involvement. Prompt administration of subcutaneous epinephrine solution 1:1000 (0.3 to 0.5 mL) and measures to ensure a patent airway may be necessary.

Discontinue aliskiren immediately in patients who develop angioedema and do not readminister.

##### **5.3 Hypotension**

An excessive fall in blood pressure (hypotension) was rarely seen (<0.5%) in patients with uncomplicated hypertension treated with Valtorna in controlled trials.

In patients with an activated renin-angiotensin-aldosterone system, such as volume- or salt-depleted patients receiving high doses of diuretics, symptomatic hypotension may occur in patients receiving renin-angiotensin-aldosterone system (RAAS) blockers. Correct these conditions prior to the administration of Valtorna, or start the treatment under close medical supervision.

Initiate therapy cautiously in patients with heart failure or recent myocardial infarction and in patients undergoing surgery or dialysis. Patients with heart failure or post-myocardial infarction patients given valsartan commonly have some reduction in blood pressure, but discontinuation of therapy because of continuing symptomatic hypotension usually is not necessary when dosing instructions are followed. In controlled trials in heart failure patients, the incidence of hypotension in valsartan-treated patients was 5.5% compared to 1.8% in placebo-treated patients. In the Valsartan in Acute Myocardial Infarction Trial (VALIANT), hypotension in post-myocardial infarction patients led to permanent discontinuation of therapy in 1.4% of valsartan-treated patients and 0.8% of captopril-treated patients.

If an excessive fall in blood pressure occurs with Valturna, place the patient in the supine position and, if necessary, give an intravenous infusion of normal saline. A transient hypotensive response is not a contraindication to further treatment, which usually can be continued without difficulty once the blood pressure has stabilized.

#### **5.4 Patients with Severe Renal Impairment**

##### Valturna

Patients with severe renal impairment were excluded from clinical trials with Valturna in hypertension.

##### Aliskiren

Patients with severe renal dysfunction (creatinine 1.7 mg/dL for women and 2.0 mg/dL for men and/or estimated GFR <30 mL/min), a history of dialysis, nephrotic syndrome, or renovascular hypertension were excluded from clinical trials of aliskiren in hypertension. Safety information with aliskiren and the potential for other drugs acting on the renin-angiotensin-aldosterone system to increase serum creatinine and blood urea nitrogen are not available.

##### Valsartan

In studies of ACE inhibitors in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen have been reported. In a 4-day trial of valsartan in 12 hypertensive patients with unilateral renal artery stenosis, no significant increases in serum creatinine or blood urea nitrogen were observed. There has been no long-term use of valsartan in patients with unilateral or bilateral renal artery stenosis, but an effect similar to that seen with ACE inhibitors should be anticipated.

As a consequence of inhibiting the renin-angiotensin-aldosterone system, changes in renal function may occur particularly in volume depleted patients. In patients with severe heart failure whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin-converting enzyme inhibitors and angiotensin receptor antagonists has been associated with oliguria or progressive azotemia and (rarely) with acute renal failure or death. Similar outcomes have been reported with valsartan.

#### **5.5 Patients with Hepatic Impairment**

##### Valsartan

As the majority of valsartan is eliminated in the bile, patients with mild-to-moderate hepatic impairment, including patients with biliary obstructive disorders, showed lower valsartan clearance (higher AUCs).

#### **5.6 Patients with Congestive Heart Failure and Post-Myocardial Infarction**

##### Valsartan

Some patients with heart failure have developed increases in blood urea nitrogen, serum creatinine, and potassium on valsartan. These effects are usually minor and transient, and they are more likely to occur in patients with pre-existing renal impairment. Dosage reduction and/or discontinuation of the diuretic and/or valsartan may be required. In the Valsartan Heart Failure Trial, in which 93% of patients were on concomitant ACE inhibitors, treatment was discontinued for elevations in creatinine or potassium (total of 1.0% on valsartan vs. 0.2% on placebo). In the Valsartan in Acute Myocardial Infarction Trial (VALIANT), discontinuation due to various types of renal dysfunction occurred in 1.1% of valsartan-treated patients and 0.8% of captopril-treated patients. Include assessment of renal function when evaluating patients with heart failure or post-myocardial infarction.

#### **5.7 Serum Electrolyte Abnormalities**

##### Valturna

In the short-term controlled trials of various doses of Valturna, the incidence of hyperkalemia (serum potassium >5.5 mEq/L) was about 1%-2% higher in the combination treatment group compared with the monotherapies aliskiren and valsartan, or with placebo.

In a long-term, uncontrolled study with median treatment duration of about one year, about 4% of the patients had at least one serum potassium >5.5 mEq/L at some time during the study; about 0.8% of patients discontinued study treatment and had a high serum potassium at some point during the study. Patients with hyperkalemia were older (median age 65 vs. 55) with slightly lower mean baseline estimated creatinine clearance compared to patients without

hyperkalemia. While about 25% of the hyperkalemic episodes occurred in the first two months, other initial episodes were reported throughout the study.

Periodic determinations of serum electrolytes to detect possible electrolyte imbalances is advised, particularly in patients at risk for hyperkalemia such as those with renal impairment.

Caution is advised with concomitant use of Valtorna with potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, or other drugs that increase potassium levels may lead to increases in serum potassium.

## 5.8 Renal Artery Stenosis

### Aliskiren

No data are available on the use of aliskiren in patients with unilateral or bilateral renal artery stenosis or stenosis of the artery to a solitary kidney.

### Valsartan

In studies of ACE inhibitors in hypertensive patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen have been reported. In a 4-day trial of valsartan in 12 hypertensive patients with unilateral renal artery stenosis, no significant increases in serum creatinine or blood urea nitrogen were observed. There has been no long-term use of valsartan in patients with unilateral or bilateral renal artery stenosis, but an effect similar to that seen with ACE inhibitors should be anticipated.

## 5.9 Cyclosporine

### Aliskiren

When aliskiren was given with cyclosporine, the blood concentrations of aliskiren were significantly increased. Concomitant use of aliskiren with cyclosporine is not recommended [see *Drug Interactions (7)*].

## 6 ADVERSE REACTIONS

### 6.1 Clinical Studies Experience

The following serious adverse reactions are discussed in greater detail in other sections of the label:

- Risk of fetal/neonatal morbidity and mortality [see *Warnings and Precautions (5.1)*]
- Head and neck angioedema [see *Warnings and Precautions (5.2)*]
- Hypotension [see *Warnings and Precautions (5.3)*]

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of another drug and may not reflect the rates observed in practice.

### Valtorna

Valtorna has been evaluated for safety in more than 1,225 patients, including over 316 patients for over 1 year. In placebo-controlled clinical trials, discontinuation of therapy because of a clinical adverse event (including uncontrolled hypertension) occurred in 1.4% of patients treated with Valtorna versus 2.7% of patients given placebo.

Adverse events in placebo-controlled trials that occurred in at least 1% of patients treated with Valtorna and at a higher incidence than placebo included fatigue (2.6% vs. 1.4%), nasopharyngitis (2.6% vs. 2.2%), diarrhea (1.4% vs. 0.9%), upper respiratory tract infection (1.4% vs. 1.1%), urinary tract infection (1.4% vs. 0.6%), influenza (1.1% vs. 0.2%), and vertigo (1.1% vs. 0.3%).

Hyperkalemia has been observed as a serum electrolyte abnormality in Valtorna clinical trials [see *Warnings and Precautions (5.7)*].

### Aliskiren

Aliskiren has been evaluated for safety in 6,460 patients, including 1,740 treated for longer than 6 months, and 1,250 for longer than 1 year. In placebo-controlled clinical trials, discontinuation of therapy because of a clinical adverse event, including uncontrolled hypertension occurred in 2.2% of patients treated with aliskiren, versus 3.5% of patients given placebo.

Two cases of angioedema with respiratory symptoms were reported with aliskiren use in the clinical studies. Two other cases of periorbital edema without respiratory symptoms were reported as possible angioedema and resulted in discontinuation. The rate of these angioedema cases in the completed studies was 0.06%.

In addition, 26 other cases of edema involving the face, hands, or whole body were reported with aliskiren use, including 4 leading to discontinuation.

In the placebo-controlled studies, however, the incidence of edema involving the face, hands, or whole body was 0.4% with aliskiren compared with 0.5% with placebo. In a long-term active-controlled study with aliskiren and HCTZ arms, the incidence of edema involving the face, hands, or whole body was 0.4% in both treatment arms.

Aliskiren produces dose-related gastrointestinal (GI) adverse reactions. Diarrhea was reported by 2.3% of patients at 300 mg, compared to 1.2% in placebo patients. In women and the elderly (age  $\geq 65$ ) increases in diarrhea rates were evident starting at a dose of 150 mg daily, with rates for these subgroups at 150 mg similar to those seen at 300 mg for men or younger patients (all rates about 2%). Other GI symptoms included abdominal pain, dyspepsia, and gastro-esophageal reflux, although increased rates for abdominal pain and dyspepsia were distinguished from placebo only at 600 mg daily. Diarrhea and other GI symptoms were typically mild and rarely led to discontinuation.

Aliskiren was associated with a slight increase in cough in the placebo-controlled studies (1.1% for any aliskiren use vs. 0.6% for placebo). In active-controlled trials with ACE inhibitor (ramipril, lisinopril) arms, the rates of cough for the aliskiren arms were about one-third to one-half the rates in the ACE inhibitor arms.

Other adverse reactions with increased rates for aliskiren compared to placebo included rash (1% vs. 0.3%), elevated uric acid (0.4% vs. 0.1%), gout (0.2% vs. 0.1%), and renal stones (0.2% vs. 0%).

Single episodes of tonic-clonic seizures with loss of consciousness were reported in two patients treated with aliskiren in the clinical trials. One patient had predisposing causes for seizures and had a negative electroencephalogram (EEG) and cerebral imaging following the seizures; for the other patient, EEG and imaging results were not reported. Aliskiren was discontinued and there was no rechallenge in either case.

The following adverse events occurred in placebo-controlled clinical trials at an incidence of more than 1% of patients treated with aliskiren, but also occurred at about the same or greater incidence in patients receiving placebo: headache, nasopharyngitis, dizziness, fatigue, upper respiratory tract infection, back pain and cough.

No clinically meaningful changes in vital signs or in ECG (including QTc interval) were observed in patients treated with aliskiren.

#### Valsartan

Valsartan has been evaluated for safety in more than 4,000 hypertensive patients in clinical trials, including over 400 treated for over 6 months, and more than 160 for over 1 year.

In trials in which valsartan was compared to an ACE inhibitor with or without placebo, the incidence of dry cough was significantly greater in the ACE inhibitor group (7.9%) than in the groups who received valsartan (2.6%) or placebo (1.5%). In a 129 patient trial limited to patients who had had dry cough when they had previously received ACE inhibitors, the incidences of cough in patients who received valsartan, HCTZ, or lisinopril were 20%, 19%, and 69% respectively ( $p < 0.001$ ).

Other adverse reactions, not listed above, occurring in  $>0.2\%$  of patients in controlled clinical trials with valsartan are:

**Body as a Whole:** allergic reaction, asthenia

**Musculoskeletal:** muscle cramps

**Neurologic and Psychiatric:** paresthesia

**Respiratory:** sinusitis, pharyngitis

**Urogenital:** impotence

Other reported events seen less frequently in clinical trials were: angioedema.

Adverse reactions reported for valsartan for indications other than hypertension may be found in the prescribing information for Diovan.

## 6.2 Clinical Laboratory Test Abnormalities

### RBC count, hemoglobin and hematocrit:

Small mean decreases from baseline were seen in RBC count, hemoglobin and hematocrit in both monotherapies and combination therapy. These changes were small, but changes in hemoglobin were slightly more pronounced with the combination therapy (-0.26 g/dL) than with monotherapy regimens (-0.04 g/dL in aliskiren or -0.13 g/dL in valsartan) or placebo (+0.07 g/dL).

### Blood Urea Nitrogen (BUN)/Creatinine:

Elevations in BUN (>40 mg/dL) and creatinine (>2.0 mg/dL) in any treatment group were less than 1.0%. For creatinine, 0.5% (3/599) of patients on combination treatment had a creatinine level >1.5 mg/dL at the end of the study and a 30% increase from baseline compared to none in either monotherapy or placebo.

Serum Electrolytes: See Warnings and Precautions (5.7)

## 6.3 Post-Marketing Experience

The following adverse reactions have been reported in aliskiren post-marketing experience. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Hypersensitivity: angioedema requiring airway management and hospitalization*

*Peripheral edema*

## 7 DRUG INTERACTIONS

No drug interaction studies have been conducted with Valturna and other drugs, although studies with the individual aliskiren and valsartan components are described below.

### **Aliskiren**

#### Effects of Other Drugs on Aliskiren

Based on *in vitro* studies, aliskiren is metabolized by CYP 3A4.

*Irbesartan:* Coadministration of irbesartan reduced aliskiren  $C_{max}$  up to 50% after multiple dosing.

*P-glycoprotein Effects:* Pgp (MDR1/Mdr1a/1b) was found to be the major efflux system involved in absorption and disposition of aliskiren in preclinical studies. The potential for drug interactions at the Pgp site will likely depend on the degree of inhibition of this transporter. Coadministration of aliskiren with Pgp substrates or weak to moderate inhibitors such as atenolol, digoxin, and amlodipine did not result in clinically relevant interactions.

*Atorvastatin:* Coadministration of atorvastatin, a weak Pgp inhibitor, resulted in about a 50% increase in aliskiren  $C_{max}$  and AUC after multiple dosing.

*Ketoconazole:* Coadministration of 200 mg twice-daily ketoconazole, a moderate Pgp inhibitor, with aliskiren resulted in approximate 80% increase in plasma levels of aliskiren. A 400-mg once-daily dose was not studied but would be expected to increase aliskiren blood levels further.

*Cyclosporine:* Coadministration of 200 mg and 600 mg cyclosporine, a potent Pgp inhibitor, with 75 mg aliskiren resulted in an approximately 2.5-fold increase in  $C_{max}$  and 5-fold increase in AUC of aliskiren. Concomitant use of aliskiren with cyclosporine is not recommended.

*Verapamil:* Coadministration of 240 mg of verapamil, a moderate Pgp inhibitor, with 300 mg aliskiren resulted in an approximately 2-fold increase in  $C_{max}$  and AUC of aliskiren. However, no dosage adjustment is necessary.

*Drugs with no clinically significant effects:* Coadministration of lovastatin, atenolol, warfarin, furosemide, digoxin, celecoxib, hydrochlorothiazide, ramipril, valsartan, metformin and amlodipine did not result in clinically significant increases in aliskiren exposure.

#### Effects of Aliskiren on Other Drugs

Aliskiren does not inhibit the CYP450 isoenzymes (CYP1A2, 2C8, 2C9, 2C19, 2D6, 2E1, and CYP 3A) or induce CYP 3A4.

*Furosemide:* When aliskiren was coadministered with furosemide, the AUC and  $C_{max}$  of furosemide were reduced by about 30% and 50%, respectively. Patients receiving furosemide could find its effect diminished after starting aliskiren.

*Drugs with no clinically significant effects:* Coadministration of aliskiren did not significantly affect the pharmacokinetics of lovastatin, digoxin, valsartan, amlodipine, metformin, celecoxib, atenolol, atorvastatin, ramipril or hydrochlorothiazide.

*Warfarin:* The effects of aliskiren on warfarin pharmacokinetics have not been evaluated.

### **Valsartan**

No clinically significant pharmacokinetic interactions were observed when valsartan was coadministered with aliskiren, amlodipine, atenolol, cimetidine, digoxin, furosemide, glyburide, hydrochlorothiazide, or indomethacin. The valsartan-atenolol combination was more antihypertensive than either component, but it did not lower the heart rate more than atenolol alone.

*Warfarin:* Coadministration of valsartan and warfarin did not change the pharmacokinetics of valsartan or the time-course of the anticoagulant properties of warfarin.

*CYP 450 Interactions:* *In vitro* metabolism studies have indicated that CYP450 mediated drug interactions between valsartan and coadministered drugs are unlikely because of low extent of metabolism [see *Pharmacokinetics – Valsartan (12.3) in the full prescribing information*].

*Transporters:* The results from an *in vitro* study with human liver tissue indicate that valsartan is a substrate of the hepatic uptake transporter OATP1B1 and the hepatic efflux transporter MRP2. Coadministration of inhibitors of the uptake transporter (rifampin, cyclosporine) or efflux transporter (ritonavir) may increase the systemic exposure to valsartan.

As with other drugs that block angiotensin II or its effects, concomitant use of potassium sparing diuretics (e.g., spironolactone, triamterene, amiloride), potassium supplements, or salt substitutes containing potassium may lead to increases in serum potassium and in heart failure patients to increases in serum creatinine.

## **8 USE IN SPECIFIC POPULATIONS**

### **8.1 Pregnancy**

Pregnancy Category D [see *Warnings and Precautions (5.1)*].

Valturna contains both aliskiren (a direct renin inhibitor) and valsartan (an angiotensin II receptor blocker). When administered during the second or third trimester of pregnancy, drugs that act directly on the renin-angiotensin-aldosterone system can cause fetal and neonatal morbidity and death. Valturna can cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus.

Angiotensin II receptor antagonists, like valsartan, and angiotensin-converting enzyme (ACE) inhibitors exert similar effects on the renin-angiotensin-aldosterone system. In several dozen published cases, ACE inhibitor use during the second and third trimesters of pregnancy was associated with fetal and neonatal injury, including hypotension, neonatal skull hypoplasia, anuria, reversible or irreversible renal failure, and death. Oligohydramnios was also reported, presumably from decreased fetal renal function. In this setting, oligohydramnios was associated with fetal limb contractures, craniofacial deformation, and hypoplastic lung development. Prematurity, intrauterine growth retardation, and patent ductus arteriosus were also reported, although it is not clear whether these occurrences were due to exposure to the drug. In addition, first trimester use of ACE inhibitors, a specific class of drugs acting on the renin-angiotensin-aldosterone system, has been associated with a potential risk of birth defects in retrospective data.

When pregnancy occurs in a patient using Valturna, discontinue Valturna treatment as soon as possible. Inform the patient about potential risks to the fetus based on the time of gestational exposure to Valturna (first trimester only or later). If exposure occurs beyond the first trimester, perform an ultrasound examination.

In rare cases when another antihypertensive agent cannot be used to treat the pregnant patient, perform serial ultrasound examinations to assess the intraamniotic environment. Routine fetal testing with non-stress tests, biophysical profiles, and/or contraction stress tests may be appropriate based on gestational age and standards of care in the community. If oligohydramnios occurs in these situations, individualized decisions about continuing or discontinuing Valturna treatment and about pregnancy management should be made by the patient, her physician, and experts in the management of high risk pregnancy. Patients and physicians should be aware that oligohydramnios may not appear until after the fetus has sustained irreversible injury.

Closely observe infants with histories of *in utero* exposure to Valtorna for hypotension, oliguria, and hyperkalemia. If oliguria occurs, these infants may require blood pressure and renal perfusion support. Exchange transfusion or dialysis may be required to reverse hypotension or support decreased renal function.

No reproductive toxicity studies have been conducted with the combination of aliskiren and valsartan. However, these studies have been conducted for aliskiren as well as valsartan alone [see *Nonclinical Toxicology (13) in the full prescribing information*].

### 8.3 Nursing Mothers

It is not known whether aliskiren is excreted in human milk, but aliskiren was secreted in the milk of lactating rats. It is not known whether valsartan is excreted in human milk. Valsartan was excreted into the milk of lactating rats; however, animal breast milk drug levels may not accurately reflect human breast milk levels. Because of the potential for adverse effects on the nursing infant, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

### 8.4 Pediatric Use

Safety and effectiveness of Valtorna in pediatric patients have not been established.

### 8.5 Geriatric Use

In the short-term controlled clinical trials of Valtorna, 99 (15.9%) patients treated with Valtorna were  $\geq 65$  years and 14 (2.2%) were  $\geq 75$  years.

No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

## 10 OVERDOSAGE

### Aliskiren

Limited data are available related to overdosage in humans. The most likely manifestation of overdosage would be hypotension. If symptomatic hypotension occurs, provide supportive treatment.

### Valsartan

Limited data are available related to overdosage in humans. The most likely effect of overdose with valsartan would be hypotension and tachycardia; bradycardia could occur from parasympathetic (vagal) stimulation. Depressed level of consciousness, circulatory collapse and shock have been reported. If symptomatic hypotension occurs, provide supportive treatment.

Valsartan is not removed from the plasma by hemodialysis.

Valsartan was without grossly observable adverse effects at single oral doses up to 2000 mg/kg in rats and up to 1000 mg/kg in marmosets, except for the salivation and diarrhea in the rat and vomiting in the marmoset at the highest dose (60 and 31 times, respectively, the maximum recommended human dose on a mg/m<sup>2</sup> basis). (Calculations assume an oral dose of 320 mg/day and a 60-kg patient.)

## 16 STORAGE

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) in original container. [See USP Controlled Room Temperature.]

Protect from moisture.

Dispense in tight container (USP).

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HRM focuses on the following:

- acquiring top-notch talent for your practice
- improving the job performance of existing employees
- retaining valuable staff
- having to intervene less often because things are less likely to go wrong

Whether or not you have day-to-day responsibility for all aspects of HR, your actions set the tone for your office and go a long way in determining whether you create a harmonious, efficient work environment. In essence, you direct the HR functions in your office through your demeanor and your decisions: The policies you create and the way you share them reflect what matters to you and what you expect from your staff. In the same vein, the budget you set aside for fostering team cohesiveness, developing staff members, or attracting and retraining strong employees makes all of these activities possible.

“Your staff will respond positively once you make the effort to become more aware of—and involved in—human resources management,” says Jeanne Stewart, SPHR, director of HR client services for Employment Practices Advisors in Northport, N.Y.

### The HR Litmus Test

Just as preventive healthcare is the best insurance against costly medical problems down the road, good HRM is the best insurance against costly HR problems and breakdowns in customer service. The best approach to avoiding HR problems is being aware of employment law and making sure that your responses to personnel issues can pass the following test:

- Is my response consistent with my previous actions?
- Is it well communicated?
- Does it match our practice’s culture and direction?
- Is it ethical and legal?
- Does it set a precedent? (Or is it sustainable?)
- Is it the right decision but the wrong time?

The best way to illustrate these criteria is with an example. Think about a valued, long-term employee who wants to work part-time hours because of child care issues at home. You’d like to grant this request, but does that response pass the test?

**Is my response consistent with my previous actions?** Have

others made requests for part-time work, and have you approved those requests? If not, were those people in this employee's same position? If so, were they all of a particular group? For instance, have you granted this request for women but not for men? Do you currently have other staff on part-time schedules?

**Is it well communicated?** Have you stated (in writing or verbally) that certain roles can be performed only on a full-time basis? Have you communicated how one should make a request for a part-time schedule and against what criteria such a request will be considered? If you haven't, are you ready to do so once you grant this employee's request? "Transparency is key to running a productive office in which few human resources problems surface," Ms. Stewart says. "Documentation of your expectations of and agreements with your staff members helps to avoid misunderstandings later."

**Does it match our practice's culture and direction?** In this situation, you can make that determination by answering these questions: Is one of the stated goals of your practice to value your employees? Do you have a flexible or a more traditionally structured workplace? Has your practice expressed a desire to experiment with alternate work arrangements (i.e., telecommuting or job sharing)? Will letting this employee work a part-time schedule take away from the work you are dedicated to doing or from meeting the needs of your patients?

**Is it ethical and legal?** If someone were to look at this decision from outside your practice, would it seem fair and above board? Would it reflect well on your practice if people were to find out that you granted this employee the time she requested? Are there potential legal ramifications that need to be explored in this situation, like those related to this employee's status, compensation, or benefits? Could those employees without children claim that those with children get more benefits?

**Does it set a precedent?** If other employees with child care issues make the same request, can you afford to grant them as well? Your decisions have to be sustainable as well as economically and administratively feasible, not just for the employee you are dealing with today, but for the one with the same situation in the future. Additionally, suggests Christine Johnson, PhD, practice enhancement facilitator at TransforMED in Leawood, Kan.,

your decision must be considered based on its influence on the whole practice and its effect on your whole team.

**Is it the right decision but the wrong time?** What if you decide to grant this employee's request today and have an influx of patients tomorrow that will make it impossible for your remaining staff to cope? That's an example of how you can make a reasonable decision at a bad time.

If you think through these questions when making decisions regarding your staff, you'll have a solid HRM strategy for your practice. "Generally if you keep these points in mind ... you will be on solid footing with your [HR] decisions and have a defense for your actions," Ms. Stewart says.

## Overcoming HR Challenges

The greatest HR challenge you are likely to face is overcoming your own perception that you simply aren't good at HR tasks and don't have enough time for them. Luckily, you can change the first obstacle with a new positive mindset—assisted by reading this issue of *Doctor's Digest*—and you can remedy the latter by re-prioritizing, re-defining, and utilizing the many resources at your disposal. Here are some strategies for getting around three of the most common complaints physicians have about HRM.

**"HR is not my job."** You probably didn't learn all the details of the business side of practice, including the employer-employee relationship, in medical school, says David Gabor, partner at Gabor & Gabor, Garden City, N.Y. On the days you don't want to deal with HR issues, revisit why you went into business in the first place and the benefits of having your own practice, he says. On the days you don't want to deal with your staff, think about how they make your practice possible. Then you can shift from a perspective of "I didn't go to medical school to end up dealing with staff issues" to "I deal with staff issues because that's what allows me to practice medicine."

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“Doctors can’t afford not to be involved in the practice’s human resources because the results of not doing it can be costly, like losing good staff to larger, higher-paying institutions,” says Fred Ralston, Jr., MD, FACP, Fayetteville Medical Associates, Fayetteville, Tenn., president of the American College of Physicians (ACP).

It may resonate most to consider your staff as your greatest investment. “The most important thing you need to do is to care



**“I’d feel better [about making HR decisions] if I knew I was following the rules.”**

**Jill S. Liebman, DO**  
Sunrise Medical Associates  
North Miami Beach, Fla.

for people. Care for who they are as individuals, not just people there to help you produce your income,” says Mary Pat Whaley, FACMPE, practice administrator for Halifax Regional Medical Center, Roanoke Rapids, N.C., and founder and editor of [www.manageyourpractice.com](http://www.manageyourpractice.com). Committing yourself to preserving and nurturing your staff is critical to the success of your practice, she says.

**“I’m not good at this.”** Several times during a half-hour conversation with *Doctor’s Digest*, Jill S. Liebman, DO, made comments like “I don’t know how to do HR properly” or “I stink at this!” But when she wasn’t lamenting how she wasn’t any good at it, she described how employees at Sunrise Medical Associates, North Miami Beach, Fla., had stayed for more than nine years, how some had even told her it was the best job they’d ever had, and where the office runs as smoothly as she’d like, with very little time spent fixing HR mistakes.

Dr. Liebman and many others who believe they’re not good at HR may actually be handling it well. Their lack of confidence stems from being unsure that what they’re doing is right or from making decisions on the fly. There’s a distinction between



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whether you can do this and whether you're confident doing it. Many doctors are more than adequate at HR but question their own performance because they're not sure what they're doing is "by the book." "I'd feel better if I knew I was following the rules," Dr. Liebman acknowledges.

There are objective ways to determine if you are actually good at HR. For instance, look at the rate of turnover in your practice, the number of lawsuits you've been involved in, how difficult it is to fill a vacancy in your practice, how many patient complaints about staff you receive. If none of these areas have been problems for you, it may be that "I'm not good at this HR stuff" is simply a negative mindset—and sometimes a self-fulfilling prophecy. Don't let an occasional isolated incident convince you that you are unable to master your HR needs.

**"I don't have time to deal with human resources."** You're not alone if you think HR is time consuming; 79% of 140 respondents replied "yes" when asked by the Medical Group Management Association (MGMA) in April, 2009, "Do human resource issues consume more of your time than you would like?" The truth is you won't always have the time to handle staff-related issues, and that can make the job more difficult and frustrating than it should be. But making a short-term time commitment to this aspect of your practice can pay off in the long run. Having certain documents and processes in place should

free up your time from misunderstandings and performance issues. Often when doctors say they have no time for HR, they're referring to the time it takes to handle a problem that has blown up and is now an urgent and messy situation. "When HR is under control, when certain protocols are in place, issues that arise are smaller and take less time to respond to," Ms. Stewart says.



**"Your office manager can handle the day-to-day aspects of your human resources management, but the manager relies on you for overall direction in creating and maintaining a collegial environment."**

**Fred Ralston, Jr., MD, FACP**  
Fayetteville Medical Associates  
Fayetteville, Tenn.

President, American College of Physicians

## Finding HR Support

Next consider who else can—with some direction from you—address your practice's HR needs. There are some aspects of the employer-employee relationship that you shouldn't relegate to someone else. "Be very careful about who intervenes for you with your staff," Ms. Whaley says. "When you put that extra layer between you and your employees, you lose something." She says items that can be most easily outsourced are the "logistical, mechanical aspects" of HR, such as payroll and some hiring. "But you shouldn't forget the day-to-day relationships, team building, and individual care for your people that you need to have regardless of who is helping you," she advises.

Here are some resources with tips on how to best coordinate them with your HR efforts:

**Your practice manager.** If you have such a person on staff, he or she can assume many HR-related tasks in your practice, says Roberta Chinsky Matuson, president of Human Resource Solutions in Northampton, Mass. "Find yourself an outstanding office manager with strong leadership and organizational skills," she says. "That individual will be able to take on much of your operations management so you can practice medicine." Questions to help screen a candidate for either position can be found

on the MGMA or TransformMED Websites.

No matter how good your hire, you'll still need to provide guidance, Dr. Ralston says. "Your office manager can handle the day-to-day aspects of your human resources management, but the manager relies on you for overall direction in creating and maintaining a collegial environment," he says. In addition, you have to know enough about HR to be able to monitor your manager's performance and to keep him or her motivated and performing at full potential.

**Current staff.** Do you use your staff to screen potential employees, help write job descriptions, organize team building and/or social events, and create a cross-training schedule? If not, you may be overlooking an available and knowledgeable resource for handling your HR needs. Employees crave autonomy and the ability to tackle new challenges. Do you need to find out how long you should retain certain documentation? Give the task of finding out to one of your promising staff members. Need to update your job descriptions? Make a person on staff that project's manager. Staff can orient new employees, conduct compensation or cost-of-living studies, or provide recognition of other staff.

**Lawyers.** If you handle your own HR, here is the number-one tip from employment lawyer Marc L. Jacuzzi, partner at Simpson, Garrity, Innes & Jacuzzi, PC in South San Francisco: "Contact a lawyer before you get sued." Doctors who contact lawyers when they are establishing (or updating) their policies, handbooks, or forms achieve legal compliance and are less likely to need a lawyer later to get them out of hot water, he explains. Mr. Gabor agrees, noting that he's seen many cases over the years that were avoidable. Both suggest you initiate a legal HR audit once a year to make sure your practice is in compliance. If your

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office manager handles your HR needs, he or she should attend the audit.

Seek out a lawyer who specializes in employment or labor law rather than a generalist, Mr. Gabor advises. “With constantly changing local, state, and federal laws to deal with, you really want to make sure your lawyer knows his or her stuff,” he explains.

Samples of legally acceptable documents and forms are usually available from your state’s Department of Labor, the U.S. Department of Labor, your state’s Division of Human Rights, or



**“It can seem almost egotistical, as a physician, to think that who you are is reflected in the culture of the whole practice, but who you are as a doctor is the foundation of your practice’s culture.”**

**John W. Ostrom, SPHR, MHSA**

Human Resources Director  
Intermountain Medical Group, Salt Lake City

the Equal Employment Opportunities Commission (EEOC). Don’t always trust Websites that advertise legally compliant HR documents, Mr. Jacuzzi warns.

**Consultants.** An HR consultant will be able to handle any aspect of your day-to-day HR and can be especially helpful for one-time projects or work outside your normal operations, such as creating or restructuring a position in your practice or conducting a cost-of-living survey. Joseph W. Stubbs, MD, MACP, ACP’s immediate past-president, points out several signs that indicate a need for you to bring on an HR consultant: “when your employees don’t know what HIPAA is, when you haven’t been able to provide ongoing information about safety, when you have a lot of turnover, or if you have no systematic way to find salary ranges.”

As with lawyers, a referral from a trusted source is the best way to find a consultant. Another resource is the Society for Human Resources Management (SHRM), the world’s largest association devoted to HRM. To find additional resources, Ms.

Whaley suggests asking your insurance broker for a referral; the broker might even offer those functions in house.

**Other resources.** SHRM's Website includes samples of effective HR policies and documents, salary surveys, publications, and blogs on HR-related topics. Associations like SHRM and certain medical associations hold local and national meetings on HR issues. If you handle your own HR, it's well worth it to become a member of SHRM; member benefits of the MGMA and ACP include assistance with HR needs. In addition, you might find HR help from local universities and hospitals with which you have partnerships.

Don't worry if the source of your HR information is not the medical community. Many HR issues and their solutions are universal. "Information that is common to both medical and non-medical employers, such as state and federal laws, or things like employment applications, interview questions, hiring and firing, and COBRA" can be applicable to medical practices, says Margo Williams, MHA, senior associate in ACP's Center for Practice Improvement and Innovation. Marc Fournier, manager of Human Resources, CORE Physicians LLC, Exeter, N.H., tells how he can apply what he learned in the retail industry to the medical field. "For example, both the retail industry and the medical practice need to instruct employees on how to manage people on the phone when there is someone standing in front of you; how you prioritize the person on the phone in relation to those who are there," he says. "It doesn't matter which industry you work in when it comes to keeping out of legal trouble with the federal and state government. HR policies that manage the workforce are just that and medical practice staff is part of the workforce."

**Technology.** Technology can be a helpful resource—but only if it fulfills a real need that you are experiencing in your practice. For instance, if you don't offer many employee benefits, you don't need a benefits administration module; if a bulletin board in the break room works for announcements, you won't



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need an “alert” function. You can buy an expensive time clock system, but many practices would do just as well with a sign-in and sign-out system. “Especially in smaller practices, a few good Excel files and some paper backup are still quite sufficient,” says Joseph Micucci, director of human resources, Methodist Hospital Division, Thomas Jefferson University Hospitals, Philadelphia.

Because the technology available to help you manage the HR aspect of your practice is evolving every day, other programs may be good investments. Mr. Micucci recommends payroll systems that track taxes and other systems that track the Fair Labor Standards Act (FLSA). You can easily outsource your payroll through ADP or another service. Software programs track time, attendance, and payroll, and HR technology can help you coordinate recruitment, legal and regulatory compliance, benefits administration, and e-learning. HR consultants who specialize in HR technology can help determine the best system for your practice (see SHRM’s Website at [www.shrm.org](http://www.shrm.org)).

### **How Involved Do You Have To Be?**

While you don’t have to be involved in managing the day-to-day HR activities of your practice, it’s critical that you provide vision and leadership. In addition, you need to set the framework for decisions to be made, direct and approve overall activities, and support your management personnel. You need to convey a positive attitude and model how you want staff members to treat each other. Therefore, before enlisting anyone’s help with your HR practices, you need to be clear about your practice’s culture—the values, processes, and relationships that surround the work being done other than output (e.g., immunizations given, tests conducted, or diagnoses provided).

“It’s difficult in small practices to realize that you have a unique culture,” says John W. Ostrom, SPHR, MHSA, human resources director, Intermountain Medical Group, Salt Lake City. “It can seem almost egotistical, as a physician, to think that who you are is reflected in the culture of the whole practice, but who you are as a doctor is the foundation of your practice’s culture.” The physician’s personality and practice style drive—or form—the practice’s culture.

How can you know what your practice's culture is? Bob Levoy, management consultant, speaker, and author of *222 Secrets of Hiring, Managing, and Retaining Great Employees in Healthcare Practices*, suggests that the process begins with prioritizing what's important to you in managing your practice. "[Does that] include, for example, clinical excellence, efficiency, cleanliness, friendliness, cost containment, thoroughness, learning, professionalism, service, or teamwork?" he asks. "Look at the policies you have in place. What are the priorities that govern the day-to-day operation of your practice? What is the rhythm and pace of your office? Where is the emphasis?"

Once you know the top priorities of your practice, then share them with your staff. "You can do that in writing or you can discuss it in a staff meeting. The point of sharing priorities is to get everyone rowing in the same direction," Mr. Levoy says. What anticipated transitions do you expect? Is a doctor in your practice retiring? Are you going to adopt an electronic health records (EHR) system? Are you going to change your office hours to meet the demands of your customers? All of these strategic business decisions will affect how you attract, retain, and manage your staff and must be communicated to employees.

### **Taking Control**

If you're one of the physicians who shies away from HR, realize that you're actually already involved in HR every day—in your interactions with office staff, in what you promote as your values and priorities, and in your responses to situations in your office. "The 'excellence in service'-minded physician can't get away from the managing and motivational portions of human resources on a day-to-day basis," says Jeffrey W. Glassheim, DO, Children's Hospital of Wisconsin, Neenah, Wis. And by becoming more familiar with HR principles and strategies you'll be more comfortable taking an active role in this essential part of your office practice.