The Bottom Line on Errors

Chapter FastFACTS

1. **Good systems can help your practice prevent the variability that leads to errors.**
2. **An error-proofing culture—e.g., scheduling procedures for patients while they're still in the office—will improve quality.**
3. **Hand-off errors can be prevented by changes in procedure and improved communication.**
4. **Avoiding diagnostic errors may be the next frontier for patient safety.**
5. **Checklists alone can't ensure safety. In addition, assess your practice and consider piggybacking others' efforts.**

The following three anecdotes, shared with *Doctor's Digest* by patients and physicians alike, demonstrate that errors in primary care occur more often—and more easily—than many physicians would like to believe.

A nurse comes into the waiting room and calls for Ann. They make small talk as they walk toward the examining room, where she records Ann's height, weight, and vital signs on an encounter sheet. Everything is going well until she asks how Ann is making out with her new reflux medication. It turns out Ann has never had reflux disease—and is Ann Jones rather than Ann Smith, whose chart the nurse is looking at. Profuse apologies ensue; but they don't reassure the patient, who switches to another primary care practice a few months later.

The doctor scribbles a prescription for antibiotic drops to treat

Indications and usage

Levemir® is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

Important safety information

Levemir® is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

Hypoglycemia is the most common adverse effect of all insulin therapies, including Levemir®. As with other insulins, the timing of hypoglycemic events may differ among various insulin preparations. Glucose monitoring is recommended for all patients with diabetes. Levemir® is not to be used in insulin infusion pumps. Any change of insulin dose should be made cautiously and only under medical supervision. Concomitant oral antidiabetes treatment may require adjustment.

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. Levemir® should not be diluted or mixed with any other insulin preparations. Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy. Dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia in patients being switched to Levemir® from other intermediate or long-acting insulin preparations. The dose of Levemir® may need to be adjusted in patients with renal or hepatic impairment.

Other adverse events commonly associated with insulin therapy may include injection site reactions (on average, 3% to 4% of patients in clinical trials) such as lipodystrophy, redness, pain, itching, hives, swelling, and inflammation.

*Whether these observed differences represent true differences in the effects of Levemir®, NPH insulin, and insulin glargine is not known, since these trials were not blinded and the protocols (eg, diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences in weight has not been established.

For your patients with type 2 diabetes,

start once-daily Levemir®

Levemir® helps patients with diabetes achieve their A1C goal.[2,3]

- 24-hour action at a once-daily dose[4,5]
- Provides consistent insulin absorption and action, day after day[4,6,7]
- Less weight gain[8]*

To access complimentary e-learning programs, visit novomedlink.com/Levemir

References: 1. Data on file. Novo Nordisk Inc, Princeton, NJ. **2.** Meneghini LF, Rosenberg KH, Koenen C, Meriläinen MJ, Lüddeke H-J. Insulin detemir improves glycaemic control with less hypoglycaemia and no weight gain in patients with type 2 diabetes who were insulin naive or treated with NPH or insulin glargine: clinical practice experience from a German subgroup of the PREDICTIVE study. *Diabetes Obes Metab.* 2007;9(3):418-427. **3.** Hermansen K, Davies M, Derezinski T, Ravn GM, Clauson P, Home P, for the Levemir Treat-to-Target Study Group. A 26-week, randomized, parallel, treat-to-target trial comparing insulin detemir with NPH insulin as add-on therapy to oral glucose-lowering drugs in insulin-naive people with type 2 diabetes. *Diabetes Care.* 2006;29(6):1269-1274. **4.** Klein O, Lynge J, Endahl L, Damholt B, Nosek L, Heise T. Albumin-bound basal insulin analogues (insulin detemir and NN344): comparable time-action profiles but less variability than insulin glargine in type 2 diabetes. *Diabetes Obes Metab.* 2007;9(3):290-299. **5.** Philis-Tsimikas A, Charpentier G, Clauson P, Ravn GM, Roberts VL, Thorsteinsson B. Comparison of once-daily insulin detemir with NPH insulin added to a regimen of oral antidiabetic drugs in poorly controlled type 2 diabetes. *Clin Ther.* 2006;28(10):1569-1581. **6.** Danne T, Endahl L, Haahr H, et al. Lower within-subject variability in pharmacokinetic profiles of insulin detemir in comparison to insulin glargine in children and adolescents with type 1 diabetes. Presented at: 43rd Annual Meeting of the European Association for the Study of Diabetes; September 17-21, 2007; Amsterdam, Netherlands. Abstract 0189. **7.** Heise T, Nosek L, Rønn BB, et al. Lower within-subject variability of insulin detemir in comparison to NPH insulin and insulin glargine in people with type 1 diabetes. *Diabetes.* 2004;53(6):1614-1620. **8.** Data on file. NDA21-536. Novo Nordisk Inc, Princeton, NJ.

Levemir®

insulin detemir (rDNA origin) injection

novo nordisk®

Please see brief summary of Prescribing Information on adjacent page.

135155-R1 November 2008

Levemir®

insulin detemir (rDNA origin) injection

Rx ONLY
BRIEF SUMMARY. Please see package insert for prescribing information.

INDICATIONS AND USAGE
LEVEMIR is indicated for once- or twice-daily subcutaneous administration for the treatment of adult and pediatric patients with type 1 diabetes mellitus or adult patients with type 2 diabetes mellitus who require basal (long acting) insulin for the control of hyperglycemia.

CONTRAINDICATIONS
LEVEMIR is contraindicated in patients hypersensitive to insulin detemir or one of its excipients.

WARNINGS
Hypoglycemia is the most common adverse effect of insulin therapy, including LEVEMIR. As with all insulins, the timing of hypoglycemia may differ among various insulin formulations.

Glucose monitoring is recommended for all patients with diabetes.

LEVEMIR is not to be used in insulin infusion pumps.

Any change of insulin dose should be made cautiously and only under medical supervision. Changes in insulin strength, timing of dosing, manufacturer, type (e.g., regular, NPH, or insulin analogs), species (animal, human), or method of manufacture (rDNA versus animal-source insulin) may result in the need for a change in dosage. Concomitant oral antidiabetic treatment may need to be adjusted.

PRECAUTIONS
General
Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. The first symptoms of hyperglycemia usually occur gradually over a period of hours or days. They include nausea, vomiting, drowsiness, flushed dry skin, dry mouth, increased urination, thirst and loss of appetite as well as acetone breath. Untreated hyperglycemic events are potentially fatal.

LEVEMIR is not intended for intravenous or intramuscular administration. The prolonged duration of activity of insulin detemir is dependent on injection into subcutaneous tissue. Intravenous administration of the usual subcutaneous dose could result in severe hypoglycemia. Absorption after intramuscular administration is both faster and more extensive than absorption after subcutaneous administration.

LEVEMIR should not be diluted or mixed with any other insulin preparations (see PRECAUTIONS, Mixing of Insulins).

Insulin may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Lipodystrophy and hypersensitivity are among potential clinical adverse effects associated with the use of all insulins.

As with all insulin preparations, the time course of LEVEMIR action may vary in different individuals or at different times in the same individual and is dependent on site of injection, blood supply, temperature, and physical activity.

Adjustment of dosage of any insulin may be necessary if patients change their physical activity or their usual meal plan.

Hypoglycemia
As with all insulin preparations, hypoglycemic reactions may be associated with the administration of LEVEMIR. Hypoglycemia is the most common adverse effect of insulins. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, use of medications such as beta-blockers, or intensified diabetes control (see PRECAUTIONS, Drug Interactions).

Such situations may result in severe hypoglycemia (and, possibly, loss of consciousness) prior to patients' awareness of hypoglycemia.

The time of occurrence of hypoglycemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen or timing of dosing is changed. In patients being switched from other intermediate or long-acting insulin preparations to once- or twice-daily LEVEMIR, dosages can be prescribed on a unit-to-unit basis; however, as with all insulin preparations, dose and timing of administration may need to be adjusted to reduce the risk of hypoglycemia.

Renal Impairment
As with other insulins, the requirements for LEVEMIR may need to be adjusted in patients with renal impairment.

Hepatic Impairment
As with other insulins, the requirements for LEVEMIR may need to be adjusted in patients with hepatic impairment.

Injection Site and Allergic Reactions
As with any insulin therapy, lipodystrophy may occur at the injection site and delay insulin absorption. Other injection site reactions with insulin therapy may include redness, pain, itching, hives, swelling, and inflammation. Continuous rotation of the injection site within a given area may help to reduce or prevent these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions may require discontinuation of LEVEMIR.

In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique.

Systemic allergy: Generalized allergy to insulin, which is less common but potentially more serious, may cause rash (including pruritus) over the whole body, shortness of breath, wheezing, reduction in blood pressure, rapid pulse, or sweating. Severe cases of generalized allergy, including anaphylactic reaction, may be life-threatening.

Intercurrent Conditions
Insulin requirements may be altered during intercurrent conditions such as illness, emotional disturbances, or other stresses.

Information for Patients
LEVEMIR must only be used if the solution appears clear and colorless with no visible particles. Patients should be informed about potential risks and advantages of LEVEMIR therapy, including the possible side effects. Patients should be offered continued education and advice on insulin therapies, injection technique, life-style management, regular glucose monitoring, periodic glycosylated hemoglobin testing, recognition and management of hypo- and hyperglycemia, adherence to meal planning, complications of insulin therapy, timing of dosage, instruction for use of injection devices and proper storage of insulin. Patients should be informed that frequent, patient-performed blood glucose measurements are needed to achieve effective glycemic control to avoid both hyperglycemia and hypoglycemia. Patients must be instructed on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, or skipped meals. Refer patients to the LEVEMIR "Patient Information" circular for additional information.

As with all patients who have diabetes, the ability to concentrate and/or react may be impaired as a result of hypoglycemia or hyperglycemia.

Patients with diabetes should be advised to inform their health care professional if they are pregnant or are contemplating pregnancy (see PRECAUTIONS, Pregnancy).

Laboratory Tests
As with all insulin therapy, the therapeutic response to LEVEMIR should be monitored by periodic blood glucose tests. Periodic measurement of HbA_{1c} is recommended for the monitoring of long-term glycemic control.

Drug Interactions
A number of substances affect glucose metabolism and may require insulin dose adjustment and particularly close monitoring.

The following are examples of substances that may reduce

the blood-glucose-lowering effect of insulin: corticosteroids, danazol, diuretics, sympathomimetic agents (e.g., epinephrine, albuterol, terbutaline), isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives).

The following are examples of substances that may increase the blood-glucose-lowering effect of insulin and susceptibility to hypoglycemia: oral antidiabetic drugs, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAO inhibitors, propoxyphene, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics.

Beta-blockers, clonidine, lithium salts, and alcohol may either potentiate or weaken the blood-glucose-lowering effect of insulin. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia. In addition, under the influence of sympatholytic medicinal products such as beta-blockers, clonidine, guanethidine, and reserpine, the signs of hypoglycemia may be reduced or absent.

The results of *in-vitro* and *in-vivo* protein binding studies demonstrate that there is no clinically relevant interaction between insulin detemir and fatty acids or other protein bound drugs.

Mixing of Insulins
If LEVEMIR is mixed with other insulin preparations, the profile of action of one or both individual components may change. Mixing LEVEMIR with insulin aspart, a rapid acting insulin analog, resulted in about 40% reduction in $AUC_{(0-2h)}$ and C_{max} for insulin aspart compared to separate injections when the ratio of insulin aspart to LEVEMIR was less than 50%.

LEVEMIR should NOT be mixed or diluted with any other insulin preparations.

Carcinogenicity, Mutagenicity, Impairment of Fertility
Standard 2-year carcinogenicity studies in animals have not been performed. Insulin detemir tested negative for genotoxic potential in the *in-vitro* reverse mutation study in bacteria, human peripheral blood lymphocyte chromosome aberration test, and the *in-vivo* mouse micronucleus test.

Pregnancy: Teratogenic Effects: Pregnancy Category C
In a fertility and embryonic development study, insulin detemir was administered to female rats before mating, during mating, and throughout pregnancy at doses up to 300 nmol/kg/day (3 times the recommended human dose, based on plasma Area Under the Curve (AUC) ratio). Doses of 150 and 300 nmol/kg/day produced numbers of litters with visceral anomalies. Doses up to 900 nmol/kg/day (approximately 135 times the recommended human dose based on AUC ratio) were given to rabbits during organogenesis. Drug-dose related increases in the incidence of fetuses with gall bladder abnormalities such as small, bilobed, bifurcated and missing gall bladders were observed at a dose of 900 nmol/kg/day. The rat and rabbit embryofetal development studies that included concurrent human insulin control groups indicated that insulin detemir and human insulin had similar effects regarding embryotoxicity and teratogenicity.

Nursing mothers
It is unknown whether LEVEMIR is excreted in significant amounts in human milk. For this reason, caution should be exercised when LEVEMIR is administered to a nursing mother. Patients with diabetes who are lactating may require adjustments in insulin dose, meal plan, or both.

Pediatric use
In a controlled clinical study, HbA_{1c} concentrations and rates of hypoglycemia were similar among patients treated with LEVEMIR and patients treated with NPH human insulin.

Geriatric use
Of the total number of subjects in intermediate and long-term clinical studies of LEVEMIR, 85 (type 1 studies) and 363 (type 2 studies) were 65 years and older. 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. In elderly patients with diabetes, the initial dosing, dose increments, and maintenance dosage should be conservative to avoid hypoglycemic reactions. Hypoglycemia may be difficult to recognize in the elderly.

ADVERSE REACTIONS
Adverse events commonly associated with human insulin therapy include the following:

Body as Whole: allergic reactions (see PRECAUTIONS, Allergy).

Skin and Appendages: lipodystrophy, pruritus, rash. Mild injection site reactions occurred more frequently with LEVEMIR than with NPH human insulin and usually resolved in a few days to a few weeks (see PRECAUTIONS, Allergy).

Other:

Hypoglycemia: (see WARNINGS and PRECAUTIONS).

In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, the incidence of severe hypoglycemia with LEVEMIR was comparable to the incidence with NPH, and, as expected, greater overall in patients with type 1 diabetes (Table 4).

Weight gain:
In trials of up to 6 months duration in patients with type 1 and type 2 diabetes, LEVEMIR was associated with somewhat less weight gain than NPH (Table 4). Whether these observed differences represent true differences in the effects of LEVEMIR and NPH insulin is not known, since these trials were not blinded and the protocols (e.g., diet and exercise instructions and monitoring) were not specifically directed at exploring hypotheses related to weight effects of the treatments compared. The clinical significance of the observed differences has not been established.

Table 4: Safety Information on Clinical Studies

			Weight (kg)		Hypoglycemia (events/subject/month)	
	Treatment	# of subjects	Baseline	End of treatment	Major*	Minor**
Type 1						
Study A	LEVEMIR	N=276	75.0	75.1	0.045	2.184
	NPH	N=133	75.7	76.4	0.035	3.063
Study C	LEVEMIR	N=492	76.5	76.3	0.029	2.397
	NPH	N=257	76.1	76.5	0.027	2.564
Study D	LEVEMIR	N=232	N/A	N/A	0.076	2.677
Pediatric	NPH	N=115	N/A	N/A	0.083	3.203
Type 2						
Study E	LEVEMIR	N=237	82.7	83.7	0.001	0.306
	NPH	N=239	82.4	85.2	0.006	0.595
Study F	LEVEMIR	N=195	81.8	82.3	0.003	0.193
	NPH	N=200	79.6	80.9	0.006	0.235

* Major = requires assistance of another individual because of neurologic impairment

** Minor = plasma glucose <56 mg/dl, subject able to deal with the episode him/herself

OVERDOSAGE
Hypoglycemia may occur as a result of an excess of insulin relative to food intake, energy expenditure, or both. Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or exercise may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. After apparent clinical recovery from hypoglycemia, continued observation and additional carbohydrate intake may be necessary to avoid reoccurrence of hypoglycemia.

More detailed information is available on request.

Rx only

Date of issue: October 19, 2005

Manufactured for Novo Nordisk Inc., Princeton, NJ 08540

Manufactured by Novo Nordisk A/S, 2880 Bagsvaerd, Denmark

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Don's scratched cornea. Don takes the prescription to the pharmacy, picks up a white bag with a small bottle in it, and opens it at home—only to find that the bottle contains eardrops, with a stern warning not to use them in the eye. Don calls the pharmacy, which blames the physician's illegible handwriting. He picks up the correct drops an hour later. His eye recovers nicely, but his faith in his doctor takes a hit.

Bob comes home from the hospital after a bout with congestive heart failure. He has on hand the furosemide his primary care physician prescribed months ago and the spironolactone that he was taking in the hospital. He takes them both on their prescribed schedules and ends up back in the hospital suffering from dehydration. At discharge a hospitalist makes sure that he's taking only one diuretic and sends him home with a list of the medications he's been prescribed during his stay. When Bob's doctor reviews the list during a follow-up office visit a few days later in order to reconcile it with the list in Bob's office chart, he makes several more changes. Now Bob is thoroughly confused. He has enough trouble keeping track of his pills without having his prescriptions changed three times in three weeks.

Given the pressures and complexities of practicing primary care today, even a professional culture of perfectionism is not enough to prevent physicians and their staffs from making mistakes. Fortunately, most errors don't cause lasting damage or spark a lawsuit. But in these tough economic times, even errors that don't cause physical harm can make healthcare providers look disorganized at best and can shake a patient's faith in their abilities (see "Medical Errors in Family Practice," opposite).

Patients' responses (e.g., finding another provider) can have a direct impact on your bottom line. In addition, administrative and billing errors not only create a bad impression on patients but may also result in lost charges or expose the practice to fraud prosecution for mistakenly overbilling. Given a regulatory climate that focuses more closely than ever on quality measures, it's critical to do everything you can to error-proof your practice.

You'll get a running start from this issue of *Doctor's Digest* as you learn how and why errors may happen in your office, how to minimize them, and how best to talk to patients about them.

Medical Errors in Family Practice

Consequences of reported events (N=330)

None	184 (55.8%)
Care consequences	
Care delayed	70 (21.2%)
Care extended	3 (0.9%)
Financial and time cost consequences	
To patients	29 (8.8%)
To physicians	16 (4.8%)
To the health system	15 (4.5%)
Patient health consequences	
Patient upset or lost trust in physician	40 (12.1%)
Patient became ill	23 (7.0%)
Patient did not regain health	8 (2.4%)
Patient admitted to hospital	10 (3.0%)
Patient died	1 (0.3%)

Source: Dovey SM et al, Quality and Safety in Health Care, *2002.*

The Greatest Challenge?

Medical errors will always be with us because people aren't perfect and medical care can be complicated. But the fragmented nature of our healthcare system practically guarantees that some kinds of errors will happen more often than they should.

The solution—and the challenge—is to create systems that perform well, according to Michael S. Barr, MD, FACP, vice president of practice advocacy and improvement at the American College of Physicians (ACP): "You can rely on individuals; but if the system isn't set up to help, you're always fighting it,"

he says. Many errors happen because physicians use dissimilar terms to describe the same condition or treatment, don't coordinate with hospitals and specialists to maintain an accurate medication list on each patient, or don't follow up on lab or radiology results.

These types of errors are understandable but could be prevented with some systemic changes, Dr. Barr says. "Most physicians are in distracting environments. Appointments are shaved smaller and smaller, so you're making decisions—sometimes complicated ones—in less time, in an environment that only pays when you see a patient. Nobody pays for you to take care

"Maybe you told a patient to follow up an office visit by getting a chest X-ray, but he didn't; so you missed diagnosing a pulmonary nodule, and the next time you see him he has advanced cancer."

Joseph W. Stubbs, MD, FACP
ACP President

of them when they're not in front of you." The ACP and other primary care professional organizations are advocating innovative payment models, like the patient-centered medical home, that give physicians breathing room to make complicated decisions without losing money. Some of those models are being tested now and may one day become the norm. (For more on the medical home, see *Doctor's Digest's* May/June 2009 issue, "Primary Care and the Medical Home," *http://www.doctorsdigest.net/issue/0503.php*)

For now, ACP president Joseph W. Stubbs, MD, FACP, thinks physicians could learn from other industries like manufacturing, in which an error-proofing culture—not just a lone employee or two—works to minimize what falls through the cracks and to improve overall quality. He acknowledges that because many primary care physicians are "mom-and-pop" operations, they don't have redundant systems in place to prevent errors. "Maybe you told a patient to follow up an office visit by getting a chest

X-ray, but he didn't; so you missed diagnosing a pulmonary nodule, and the next time you see him he has advanced cancer," he says. Some practices avoid that particular scenario by having the patient wait in the office after his appointment while a clerk calls the imaging center and schedules his procedure.

The Future Is Now

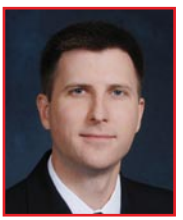
A seismic shift in the medical profession's approach to errors happened a decade ago when the Institute of Medicine (IOM) published its study *To Err is Human: Building a Safer Healthcare System*. (For the full report, see *http://www.nap.edu/catalog.php?record_id=9728*.) Although progress on the recommendations has been slow, it has been steady enough that the changes hoped for by 2020 are taking shape.

The committee that created the study was surprised at the impact it had, since it was based on old research and its broad outlines were well known in the profession, says Joseph Scherger, MD, a family practitioner who was on the IOM committee and is now busy redesigning care delivery in Rancho Mirage, Calif., as vice president for primary care at Eisenhower Medical Center.

"We thought we were just consolidating the available data," Dr. Scherger says. "But what happened was that we finally had the tools and methods to fix things, so the situation was no longer tolerable." He notes that the committee's call to end

physician handwriting in charts and orders, and to encourage the use of electronic medical records (EMRs), electronic prescribing, and good clinical decision support systems are all well underway. "What we called for in ten years is going to take fifteen or twenty, but it's all happening now," he says.

The report (and its 2001 sequel, *Crossing the Quality Chasm* at *http://www.nap.edu/catalog.php?record_id=10027*.) caught the attention of the general public and ended up rocking the entire medical care establishment. Hospitals can no longer make extra money from Medicare by treating hospital-acquired infections or the fallout from other "never events" like performing



"The variability in processes, or in some cases the lack of processes, is a contributor to mistakes and errors that happen in the outpatient setting, which is generally less structured than a hospital."

Jeff Brady, MD
Head, AHRQ's Patient Safety Portfolio

wrong-site surgery or leaving sponges inside a patient. Instead, they have to eat the costs. Practice protocols are increasingly replacing seat-of-the-pants judgments by individual physicians, reducing variations in care that at their extremes could be considered wrong. In a clear sign that concern over quality healthcare has finally gone mainstream, Brent C. James, MD, executive director at the Institute for Health Care Delivery Research at Intermountain Health Care in Utah, was featured on the cover of *The New York Times Magazine* in November. A long feature extolled his influential work on evidence-based medicine.

Giving excellent care is no longer just a matter of applying the knowledge and skills learned in medical school and years of practice. Medical care is increasingly provided by an entire web of parties who need to communicate reliably with one another. "The research shows that most errors center on communication, or [the] lack thereof," says Bruce Bagley, MD, medical director for quality improvement with the American Academy of Family

Physicians (AAFP). "A lot of verbal communication isn't completed, or isn't done with read-back and feedback, to make sure the other person understands what was said."

Office Practices: Special Challenges

Much of the public attention on medical errors is focused on hospitals. That's where the mistakes that garner much of the media focus are most likely to occur—wrong-site surgery, a critically ill patient forgotten in a crowded emergency room, or a movie star's twin newborns almost killed with an overdose of heparin. But even though they may be less widely publicized, many serious errors occur in private practices as well. And the Agency for Healthcare Research and Quality (AHRQ), the government agency most concerned with reducing mistakes and improving patient safety, recognizes that in some ways the errors that occur in outpatient practices may be more difficult to control.

"The variability in processes, or in some cases the lack of processes, is a contributor to mistakes and errors that happen in the outpatient setting, which is generally less structured than a hospital," says Jeff Brady, MD, head of AHRQ's patient safety portfolio. Outpatient practices are substantially less likely than hospitals to have an organized infrastructure for quality improvement, to do regular peer review, and to have electronic health record (EHR) systems, Dr. Brady says. And all of those deficits make it harder to track errors and to make changes to prevent them.

The single largest source of medical error, regardless of the setting, is medication errors (see "Warfare on Warfarin Errors Yields Results," page 18). Other major sources of error include bad communication during hand-offs between hospitals and physicians (or between primary care physicians and specialists),

as well as diagnostic errors.

A 2007 IOM study estimated that there were 530,000 preventable drug injuries every year in outpatient settings among Medicare beneficiaries alone, and that number doesn't include errors that were caught and corrected before they did any damage or weren't serious enough to cause injury. (For the full IOM study, see *http://www.nap.edu/catalog.php?record_id=11623*.) The true annual outpatient medication error rate is at least 1.5 million people every year, according to a report from the Institute of Medicine of the National Academies. "It's a staggering problem, and our healthcare system can't afford it," says Russell H. Jenkins, MD, medical director of the Horsham, Pa.-based Institute for Safe Medication Practices (ISMP). Illegible handwriting, ambiguous abbreviations, sound-alike drug names, and unclear dosing instructions combine to create plenty of

Warfare on Warfarin Errors Yields Results

Some errors are so common and potentially disastrous that they warrant a systemic solution all their own. The blood thinner warfarin, a routine lifesaver for many cardiac patients, can cause dangerous bleeding and is one of the most common causes of adverse drug events. It can be a challenge to establish the right dose when the patient is new to the drug, says Jeff Brady, MD, of the Agency for Healthcare Research and Quality (AHRQ). Moreover, excellent provider-patient communication is more important than usual, because the patient's diet and activities can compromise the drug's effectiveness and safety.

A $600,000 AHRQ grant helped establish the Community Anticoagulation Therapy Clinic in Cedar Rapids, Iowa, a collaboration among several area providers. The clinic, started in 2006, focuses on more than 200 patients on warfarin, monitoring them closely to make sure their dosage is in the correct range, and educating them on complying with instructions.

The clinic has improved patients' warfarin experience across the board. They are less likely than non-clinic patients to

- miss doses
- require dose changes
- have bleeding and clotting events
- end up in the hospital, or even in an emergency room, because of their anti-coagulants

For more information, visit *http://crhealthcarealliance.org/*.

potential for missteps, he says. (See Chapter 2 for tips on preventing medication errors.)

Diagnostic Errors—'The Next Frontier'

A visit to the Department of Diagnostic Medicine in TV's *House* is almost always an exercise in ill-founded hypotheses, inadequate or excessive testing, too-hasty treatment, disaster, and near-death. Actual physicians may be perplexed that the fictional team isn't sued more often—even several times a week. In the real world, diagnostic errors are a common source of preventable harm and a frequent cause of litigation. A Harvard study in the early 1990s showed that physicians were more likely to harm hospital patients with diagnostic errors than with medication errors, and that diagnostic errors were three times more likely than medication errors to result in serious disability.

A March 2009 *JAMA* commentary called diagnostic errors "the next frontier for patient safety" and advocated, among other things, the training of real Dr. Houses (though presumably with more acumen and less drama). Authors David Newman-Toker, MD, and Peter Pronovost, MD, of Johns Hopkins University believe that diagnostic errors are too multifaceted to respond to any one solution (for example, computerized decision support systems). They suggest the following:

- Renewing an emphasis on traditional clinical skills during medical training
- Exploring new methods like simulation or gaming
- Making major improvements in health information technology
- Funding research into diagnostic problems in order to build knowledge repositories for better decision making
- Creating multidisciplinary training paths for clinical experts who specialize in diagnosis

Like treatment errors, diagnostic errors fall into patterns. A

study in the November 9, 2009, *Archives of Internal Medicine* looked at 583 error reports gathered by mail and during grand rounds presentations. The two most commonly missed diagnoses were pulmonary embolism and drug reactions, each of which accounted for 4.5% of the total. But if all types of cancer cases were added, they accounted for more than one-fifth of missed diagnoses. The research team used the reports to develop a classification tool that broke down the diagnostic process into seven stages and several steps within each stage to pinpoint where the errors occurred. The weakest link overall was lab and radiology testing, including delays in ordering the tests and failure to look at the results. The second weakest was the clinician's assessment, including failure or delay in considering the diagnosis, wrongly weighing or prioritizing the possible diagnoses, and failure to recognize urgency or complications.

Beyond the Checklist

On the last episode of the long-running drama *ER* last April, one main character was about to get a kidney transplant when another whipped out his "safe surgery checklist" and irked the chief surgeon by taking a minute to run through it before the cutting started. Of course, one of the provisions ended up saving the kidney and the patient; and one of the surgical residents inquired where he could get a copy of that checklist. The scene may have marked the first time that an error-reduction protocol was given prominence on a major network drama.

"You know something's entered the culture when it shows up on TV," says Nancy Berlinger, deputy director and research scholar at the Hastings Center, a bioethics research institution in Garrison, N.Y. Ms. Berlinger, who wrote the chapter on medical errors in the center's *Bioethics Briefing Book*, says cultural issues are at the heart of creating a care environment that minimizes the chance for errors and maximizes the likelihood that they'll be caught before they do damage. She strongly recommends that practices start by using the Physician Patient Safety Assessment Survey to diagnose the state of their patient safety culture and identify the first steps for improving it (see "The First Step in Error-proofing Your Practice," opposite).

Ms. Berlinger believes that a culture of perfection may do

more harm than good, because perfection is not an attainable goal and some errors are inevitable. "Systems designed to catch human error are better," she says. A culture of perfection may also blind office physicians to patterns of error that signal the need for a change in the way they practice.

While it's tempting to believe that relying on lists and protocols will fix everything, it's not enough, as Hopkins's Dr. Pronovost and several colleagues pointed out in the August 8, 2009, issue of *The Lancet*. Although they can be useful, checklists are a result of better safety systems, not a cause. Consequently, adopting them blindly may not improve your practice if you don't go through the process of understanding and embrac-

The First Step in Error-proofing Your Practice

Experts agree that the biggest threat to patient safety isn't incompetent physicians, but bad systems. The first step to error-proofing your practice is to evaluate how well its systems protect your patients and pinpoint areas that need to change. To help you, there's the Physician Practice Patient Safety Assessment, introduced in 2006 and developed jointly by the Healthcare Research and Education Trust, the Institute for Safe Medication Practices, and the Medical Group Management Association. The survey tool lets both physicians and staff give their impressions of how well things are working; and if you choose to pay the fee to complete the survey online, you can see how your practice compares with other practices that have taken it. (You can download the questionnaire free to take a look.) The assessment covers the following topics:

- medication safety
- patient handoffs and transitions
- surgery and invasive procedures
- personnel qualifications and competency
- practice management and culture
- patient education and communication

New in 2009 are several additional free publications to help practices use the information they glean from the initial assessment in the areas of teambuilding, medication safety, and a culture of safety. At this writing there's also a free Webinar on using the tools. It's all at *http://www.physiciansafetytool.org.*

ing the reasoning behind every item.

As the authors said: "Safer care is achieved when all three—not just one—of the following are realized: summarize and simplify what to do, measure and provide feedback on outcomes, and improve culture by building expectations of performance standards into work processes. We propose that widespread deployment of checklists without an appreciation of how or why they work is a potential threat to patients' safety and to high-quality care."

Choose Your Partner

With healthcare organizations across the country—Intermountain, the Mayo Clinic network, and Partners Health System in Boston, for example—working to improve care and reduce errors, your practice may benefit by piggybacking on existing efforts in your area. Eisenhower Medical Center's Dr. Scherger says one strategy, whether you're in a large group or a one-doctor practice, is to join or affiliate with a larger entity that's known for high-quality care, and embrace its processes as your own. "Physician office care is a cottage industry, and there's no accreditation mechanism like there is for hospitals, so it's hard to regulate quality," he says. "It's like trying to regulate food safety in the corner grocery store."

An affiliation with the right institution can raise not only the quality of the care you provide, but also the public perception of your practice. "If you drive into any small town or suburb in America and see a Starbucks, you know exactly what's going to happen in there, and the same with McDonald's or the Bank of America," he says. "If there's just a shingle outside your office with your name, people don't know what's going on inside. If your shingle says, 'Member of the Mayo Network,' you're going to be perceived differently. You have to align yourself with an integrated delivery system."

Dr. Scherger is currently trying to build just such a physician network with the medical center as its hub. Participating practices will carry the "Eisenhower Medical Associates" brand. Part of his initiative is "Eisenhower 365," a group of practices that will operate on the medical home model and make extensive use of electronic communications and records to keep office visit

volume low. At this writing, the model was due to launch early in 2010.

To Err Is Human

Dr. Jenkins of the ISMP sees a major cultural shift coming in how the medical profession views errors—as something to be anticipated and dealt with, rather than as something that should never happen. "The biggest thing in the next five years will be that we recognize we're human and make errors," he says. A growing number of tools will help avert errors by catching dangerous orders and prescriptions before they're executed. Even now the Food and Drug Administration (FDA) is asking physicians to help identify and prevent the most serious medication errors (see "The FDA Steps in on Medication Errors, below).

Still other tools will help change systems so that it's easier to do the right things and difficult or impossible to do the wrong ones. "Information technology will have a huge impact on medication safety because it will allow things to be done in a standardized way and gather information that we can't gather now," Dr. Jenkins says.

The FDA Steps in on Medication Errors

The Food and Drug Administration (FDA) is calling on physicians as well as other healthcare providers and stakeholders to help identify the most serious medication errors and find ways to prevent them through its Safe Use Initiative, launched last November.

Within the first year, the initiative is scheduled to put together specific cases for "collaborative analysis and intervention"; develop estimates of preventable harm from medications (categorized by drug, drug class, and therapeutic situation); and collect public comments, both in writing and via meetings, on the best areas to focus its efforts, and what kinds of interventions would be most effective. It will then choose a few specific interventions to test, and finally measure the results.

For more information, visit *http://www.fda.gov/Drugs/DrugSafety/ucm187806.htm.*