

# Most Doctors Face a Malpractice Claim by Age 65

VITALS

**Major Finding:** Among the 7.4% of physicians who face medical malpractice claims every year, only 1.6% result in compensation paid to the plaintiff.

**Data Source:** An analysis of the malpractice claims of 40,916 physicians from 25 different specialties, from 1991 to 2005.

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BY FRANCES CORREA

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Although physicians in high-risk specialties face a near certainty of a malpractice claim at some point in their careers, only a small minority will end up making an indemnity payment to a patient.

The probability of facing a malpractice claim increases with length of time in practice, based on data from 1991 through 2005 from a large national malpractice carrier insuring more than 40,000 physicians in all 50 states and the District of Columbia.

Among physicians in high-risk specialties such as neurosurgery, general surgery, and obstetrics/

gynecology, an estimated 88% were projected to face their first claim by age 45 and an estimated 99% by age 65. In low-risk specialties such as family medicine, pediatrics, and psychiatry, 36% of physicians were projected to face their first claim by age 45 years and 75% by age 65 years, Dr. Anupam Jena of Harvard Medical School and his colleagues wrote.

In contrast, the projected rates of indemnity claims paid to plaintiffs were lower. By age 45, 33% of physicians in high-risk specialties were projected to have had a claim paid, rising to 71% by age 65 years. For physicians in low-risk specialties, 5% were projected to have had a claim paid by age 45 years, rising to 19% by age 65 years (N. Engl. J. Med. 2011;365:629-36).

"If you've hit 65 and you haven't had a claim, that's rare; that's almost impossible in our data," Dr. Jena said in an interview, adding that high-risk specialties often come with higher salaries, which could be what balances out the risk factor for physicians.

Overall, 7.4% of physicians were sued for malpractice each year of the study, with 1.6% having an indemnity payment made each year. Specialties in which physicians were more likely to face a malpractice claim were not the ones where indemnity payments were most prevalent, Dr. Jena and his coauthors wrote.

For example, 19.1% of neurosurgeons faced a claim each year, according to the analysis, compared to 3.1% of pediatricians. However, the average indemnity payment for neurosurgeons was \$344,811, lower than the average of \$520,924 for pediatricians.

While few claims resulted in payment, researchers said they were surprised by how many physicians face malpractice claims every year.

"A lot of those claims do not resolve in a payment to the patient, but they still involve significant monetary costs to both the physician and the insurer," Dr. Jena said. "The physician has loss of productivity because they're not able to see patients as they defend cases ... and then there are all sorts of nonmonetary costs that we simply cannot measure," Dr. Jena said in an interview.

Among all specialties, neurosurgery had the yearly highest risk of being sued (19.1%), followed by thoracic-cardiovascular surgery (18.9%), and general surgery (15.3%). Specialties with the lowest yearly risk of facing being sued included psychiatry (2.6%), pediatrics (3.1%), and family medicine (5.2%). The average payment for all specialties was \$273,887.

Some lawmakers and health care organizations have advocated for national medical malpractice reform, or tort reform, as a means of lowering health care costs; California and Texas already have \$250,000 caps noneconomic damages. However, there's little evidence that proves these measures are lowering health care costs. Even without tort reform, Dr. Jena said that he believes the best solution is one that roots out frivolous claims. ■

## • Insulin initiation and intensification of glucose control

Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy.

## • Lipodystrophy

Long-term use of insulin, including LANTUS, can cause lipodystrophy at the site of repeated insulin injections. Lipodystrophy includes lipohypertrophy (thickening of adipose tissue) and lipoatrophy (thinning of adipose tissue), and may affect insulin absorption. Rotate insulin injection or infusion sites within the same region to reduce the risk of lipodystrophy. [See *Dosage and Administration (2.1)*].

## • Weight gain

Weight gain can occur with insulin therapy, including LANTUS, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.

## • Peripheral Edema

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

## • Allergic Reactions

### Local Allergy

As with any insulin therapy, patients taking LANTUS may experience injection site reactions, including redness, pain, itching, urticaria, edema, and inflammation. In clinical studies in adult patients, there was a higher incidence of treatment-emergent injection site pain in LANTUS-treated patients (2.7%) compared to NPH insulin-treated patients (0.7%). The reports of pain at the injection site did not result in discontinuation of therapy.

Rotation of the injection site within a given area from one injection to the next may help to reduce or prevent these reactions. 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. Most minor reactions to insulin usually resolve in a few days to a few weeks.

### Systemic Allergy

Severe, life-threatening, generalized allergy, including anaphylaxis, generalized skin reactions, angioedema, bronchospasm, hypotension, and shock may occur with any insulin, including LANTUS and may be life threatening.

## • Antibody production

All insulin products can elicit the formation of insulin antibodies. The presence of such insulin antibodies may increase or decrease the efficacy of insulin and may require adjustment of the insulin dose. In phase 3 clinical trials of LANTUS, increases in titers of antibodies to insulin were observed in NPH insulin and insulin glargine treatment groups with similar incidences.

## 6.2 Postmarketing experience

The following adverse reactions have been identified during post-approval use of LANTUS.

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency or establish a causal relationship to drug exposure.

Medication errors have been reported in which other insulins, particularly short-acting insulins, have been accidentally administered instead of LANTUS [See *Patient Counseling Information (17) in the full prescribing information*]. To avoid medication errors between LANTUS and other insulins, patients should be instructed to always verify the insulin label before each injection.

## 7. DRUG INTERACTIONS

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

The following are examples of drugs that may increase the blood-glucose-lowering effect of insulins including LANTUS and, therefore, increase the susceptibility to hypoglycemia: oral anti-diabetic products, pramlintide, angiotensin converting enzyme (ACE) inhibitors, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, propoxyphene, pentoxifylline, salicylates, somatostatin analogs, and sulfonamide antibiotics.

The following are examples of drugs that may reduce the blood-glucose-lowering effect of insulins including LANTUS: corticosteroids, niacin, danazol, diuretics, sympathomimetic agents (e.g., epinephrine, albuterol, terbutaline), glucagon, isoniazid, phenothiazine derivatives, somatropin, thyroid hormones, estrogens, progestogens (e.g., in oral contraceptives), protease inhibitors and atypical antipsychotic medications (e.g. olanzapine and clozapine).

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.

## LANTUS® (insulin glargine [rDNA origin] injection) solution for subcutaneous injection

The signs of hypoglycemia may be reduced or absent in patients taking sympatholytic drugs such as beta-blockers, clonidine, guanethidine, and reserpine.

## 8. USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

Pregnancy Category C: Subcutaneous reproduction and teratology studies have been performed with insulin glargine and regular human insulin in rats and Himalayan rabbits. Insulin glargine was given to female rats before mating, during mating, and throughout pregnancy at doses up to 0.36 mg/kg/day, which is approximately 7 times the recommended human subcutaneous starting dose of 10 Units/day (0.008 mg/kg/day), based on mg/m<sup>2</sup>. In rabbits, doses of 0.072 mg/kg/day, which is approximately 2 times the recommended human subcutaneous starting dose of 10 Units/day (0.008 mg/kg/day), based on mg/m<sup>2</sup>, were administered during organogenesis. The effects of insulin glargine did not generally differ from those observed with regular human insulin in rats or rabbits. However, in rabbits, five fetuses from two litters of the high-dose group exhibited dilation of the cerebral ventricles. Fertility and early embryonic development appeared normal.

There are no well-controlled clinical studies of the use of LANTUS in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is essential for patients with diabetes or a history of gestational diabetes to maintain good metabolic control before conception and throughout pregnancy. Insulin requirements may decrease during the first trimester, generally increase during the second and third trimesters, and rapidly decline after delivery. Careful monitoring of glucose control is essential in these patients.

### 8.3 Nursing Mothers

It is unknown whether insulin glargine is excreted in human milk. Because many drugs, including human insulin, are excreted in human milk, caution should be exercised when LANTUS is administered to a nursing woman. Use of LANTUS is compatible with breastfeeding, but women with diabetes who are lactating may require adjustments of their insulin doses.

### 8.4 Pediatric Use

The safety and effectiveness of subcutaneous injections of LANTUS have been established in pediatric patients (age 6 to 15 years) with type 1 diabetes [see *Clinical Studies (14) in the full prescribing information*]. LANTUS has not been studied in pediatric patients younger than 6 years of age with type 1 diabetes. LANTUS has not been studied in pediatric patients with type 2 diabetes.

Based on the results of a study in pediatric patients, the dose recommendation when switching to LANTUS is the same as that described for adults [see *Dosage and Administration (2.3) and Clinical Studies (14) in the full prescribing information*]. As in adults, the dosage of LANTUS must be individualized in pediatric patients based on metabolic needs and frequent monitoring of blood glucose.

### 8.5 Geriatric Use

In controlled clinical studies comparing LANTUS to NPH insulin, 593 of 3890 patients (15%) with type 1 and type 2 diabetes were ≥65 years of age and 80 (2%) patients were ≥75 years of age. The only difference in safety or effectiveness in the subpopulation of patients ≥65 years of age compared to the entire study population was a higher incidence of cardiovascular events typically seen in an older population in both LANTUS and NPH insulin-treated patients.

Nevertheless, caution should be exercised when LANTUS is administered to geriatric patients. 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 [See *Warnings and Precautions (5.3)*].

## 10. OVERDOSAGE

An excess of insulin relative to food intake, energy expenditure, or both may lead to severe and sometimes prolonged and life-threatening hypoglycemia. Mild episodes of hypoglycemia can usually be treated with oral carbohydrates. Adjustments in drug dosage, meal patterns, or exercise may be needed.

More severe episodes of hypoglycemia 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 recurrence of hypoglycemia.

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sanofi-aventis U.S. LLC

Bridgewater, NJ 08807

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