

Legal Issues

By Janet K. Feldkamp, JD, RN, LNHA

Violations of nursing standards of care can result in actions against individuals, survey deficiencies, civil money penalties for long-term care facilities, and a variety of other possible negative outcomes. Two cases demonstrate how nurses are in personal jeopardy.

In 2005, a Delaware court upheld a

finding that the state's nursing standard of care requires a licensed nurse to perform cardiopulmonary resuscitation, if possible, and contact 911 for any full-code patient in full arrest.

The 79-year old woman in the case was a resident of a skilled nursing facility, diagnosed with a variety of chronic illnesses but identified as "full code" in

Facilities at Risk When Nurses Violate Standards

her medical record. One afternoon, a certified nursing assistant noticed a change in the resident's status, including the presence of a thick white discharge coming from her mouth. The nursing assistant called a registered nurse to the room.

The RN observed the resident and repositioned her, at which time blood be-

gan streaming from the woman's nose. The RN then checked the patient's pulse, but he did not attempt to perform CPR or call 911. Instead, the RN called the charge nurse and instructed her to come to the resident's room and to bring her stethoscope. The RN did not indicate any urgency regarding the situation when he called the charge nurse. The

Medical Expert Perspective

These cases highlight several important points. The standard of care is not the same as optimal care, or the best possible care. It's merely that level of care or skill that a reasonably prudent professional of that training or licensure should provide in that or a similar situation. Even making an incorrect decision is not necessarily negligent.

While expert testimony is required to determine the standard of care in civil cases, attorneys often attempt to invoke other definitions of standards of care. These may include state or federal regulations, guidelines, and facilities' policies and procedures.

In fact, failure to follow a facility's policy or procedure may not be a breach of the standard of care, but it doesn't look good. Try to ensure that your policies and procedures are reasonable and achievable, and do the same for care plan goals.

Another point here is that even if an individual health care worker is negligent, the facility can be implicated under the notion that it is responsible for the acts of employees – and it is much easier for a plaintiff to prevail against a corporate or institutional entity than an individual.

Finally, the whole idea that somehow the outcomes would have been different if cardiopulmonary resuscitation had been performed on the individuals in these cases is misguided. The survival rates for out-of-hospital arrests with CPR are dismal.

We need to educate our patients about this before casually signing "full code" orders. Performing CPR on a frail elderly nursing home resident is not a kindness, and people really ought to give informed consent for it to happen. Perhaps allowing them to watch a video of a full code situation – and its results for a patient even if he or she survives – would evoke a truly informed decision.

–Karl Steinberg, MD, CMD
Editor in Chief

Step up to a range of insulin delivery options.



As part of Eli Lilly and Company's ongoing commitment, we provide healthcare facilities with a choice of vial sizes.

Humalog® (insulin lispro injection [rDNA origin]), Humulin® R U-100 (regular insulin human injection, USP [rDNA origin]), and Humulin® N (NPH human insulin [rDNA origin] isophane suspension) are available in a smaller vial size.*

The smaller vials are designed to give healthcare facilities flexibility when evaluating insulin storage and distribution (floor stock vs individual patient supply), in addition to the 10 mL vial and Humalog® KwikPen™.

- Humalog Smaller Vial* NDC Number - 0002-7510-17
- Humulin R U-100 Smaller Vial* NDC Number - 0002-8215-17
- Humulin N Smaller Vial* NDC Number - 0002-8315-17

* Smaller vials contain 3 mL of insulin in a 5 mL vial.

Humalog Indication

Humalog (insulin lispro injection [rDNA origin]) is for use in patients with diabetes mellitus for the control of hyperglycemia. Humalog should be used with longer-acting insulin, except when used in combination with sulfonylureas in patients with type 2 diabetes.

Humalog Important Safety Information

Contraindications

Humalog is contraindicated during episodes of hypoglycemia and in patients sensitive to Humalog or one of its excipients.

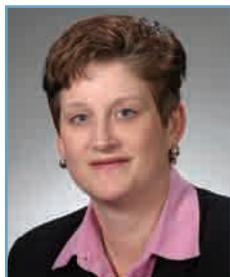
Warnings

Humalog differs from regular human insulin by its rapid onset of action as well as a shorter duration of action. Therefore, when used as a mealtime insulin, Humalog should be given within 15 minutes before or immediately after a meal.

Due to the short duration of action of Humalog, patients with type 1 diabetes also require a longer-acting insulin to maintain glucose control (except when using an insulin pump).

Glucose monitoring is recommended for all patients with diabetes.

The safety and effectiveness of Humalog in patients less than 3 years of age have not been established. There are no adequate and well-controlled clinical studies of the use of Humalog in pregnant or nursing women.



Janet K. Feldkamp

Delaware's Adult Abuse Registry for violating the nursing standard of care when he failed to perform CPR or call

resident died without emergency intervention.

The RN was charged with neglect by the state's Department of Health and Social Services and was placed on

911 for the full-code patient. The RN argued that there was insufficient evidence to prove that he had violated a standard of care and that the patient was "obviously" dead when he arrived in the room. However, the court disagreed and found that the procedure for responding to a full-code patient in full arrest is to perform CPR and call 911.

The RN also argued that the failure to perform CPR was merely a violation of an internal facility policy, not of the state's nursing standard of care. The court again disagreed.

In a 2010 case, a New York court found

that failure to properly and immediately perform CPR may be grounds for a claim of nursing malpractice. The patient involved was a 12-year-old girl who was receiving home infusions of a steroid administered by a visiting nurse.

After commencement of one of the infusions, the patient, lying on a sofa, began to complain of difficulty breathing. The situation quickly escalated, and the patient went into arrest. The nurse did administer CPR to the patient, but there was conflicting testimony as to whether it took place on the sofa or the floor.

Expert testimony in the case estab-

lished that if CPR was performed on the sofa, the nurse had improperly administered the procedure because it should be performed on a sturdy, rigid surface. Although this particular case addressed the administration of CPR in a home-care setting, the court (in ruling that a trial should occur) said that the proper administration of CPR is a basic standard of nursing care and could be raised in the malpractice case.

Long-term care facilities also can be found noncompliant with standards of care, and the result can be a per-day

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Humalog Important Safety Information, continued

Warnings, continued

Starting or changing insulin therapy should be done cautiously and only under medical supervision.

Hypoglycemia

Hypoglycemia is the most common adverse effect associated with insulins, including Humalog. Hypoglycemia can happen suddenly, and symptoms may be different for each person and may change from time to time. Severe hypoglycemia can cause seizures and may be life-threatening.

Other Side Effects

Other potential side effects associated with the use of insulins include: hypokalemia, weight gain, lipodystrophy, and hypersensitivity. Systemic allergy is less common, but may be life-threatening. Because of the difference

Humalog Important Safety Information, continued

Other Side Effects, continued

in action of Humalog, care should be taken in patients in whom hypoglycemia or hypokalemia may be clinically relevant (eg, those who are fasting, have autonomic neuropathy or renal impairment, are using potassium-lowering drugs, or taking drugs sensitive to serum potassium level).

Please see adjacent pages for Brief Summary of full Prescribing Information for Humalog.

Please see full user manual that accompanies the pen.

Humalog® and Humalog® KwikPen™ are registered trademarks of Eli Lilly and Company and are available by prescription only.

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insulin lispro injection (rDNA origin)



REGULAR insulin human injection, USP (rDNA origin)



NPH human insulin (rDNA origin) isophane suspension



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penalty for as long as a court determines a resident was in immediate jeopardy because of the facility's failure. For example, in the case of Life Care Center of Tullahoma, Tenn., a Centers for Medicare & Medicaid administrative law judge found that the nursing home failed to adhere to Medicare facilities' standard of care, established by F Tag 281, when nurses routinely didn't notify patients' physicians of hypoglycemia or hyperglycemia. The facility was fined \$4,550 per day for a total of \$709,800.

Life Care argued that it was being held to a standard of care not found in the applicable regulations. However, the CMS appeals board agreed with the administrative law judge that Life Care's clinical staff had failed to adhere to professional standards of quality as required by F Tag 281. Furthermore, the appeals board stated that the prevailing standard of care was corroborated by the existence of the facility's own physician-notification protocol and hyperglycemia and hypoglycemia policy, both of which demonstrate the appropriate standard of care.

Even though each licensed nurse is responsible for his or her practice and competence, the facility must provide policies and procedures with appropriate oversight and management to ensure that nurses' care complies with standards of practice. A facility's medical director is an integral component in the development of policies and the ongoing monitoring of care.

Education and reinforcement of the facility's policies can update the staff regarding changes in skills and knowledge required for the delivery of quality care.

Breach of a standard of care by a li-

censed nurse in a long-term care setting may result in significant monetary penalties to the nurse and the facility.

This column is not to be substituted for legal advice. The writer, JANET K. FELDKAMP, practices in various aspects of health care, including long-term care survey and certification, certificate of need, health care acquisitions, physician and nurse practice, managed care and nursing related issues, and fraud and abuse. She is affiliated with Benesch Friedlander Coplan & Aronoff LLP of Columbus, Ohio.

HUMALOG®

INSULIN LISPRO INJECTION (rDNA ORIGIN)

BRIEF SUMMARY: Consult package insert for complete prescribing information.

INDICATIONS AND USAGE: Humalog is an insulin analog that is indicated in the treatment of patients with diabetes mellitus for the control of hyperglycemia. Humalog has a more rapid onset and a shorter duration of action than regular human insulin. Therefore, in patients with type 1 diabetes, Humalog should be used in regimens that include a longer-acting insulin. However, in patients with type 2 diabetes, Humalog may be used without a longer-acting insulin when used in combination therapy with sulfonylurea agents.

Humalog may be used in an external insulin pump, but should not be diluted or mixed with any other insulin when used in the pump. Humalog administration in insulin pumps has not been studied in patients with type 2 diabetes.

CONTRAINDICATIONS: Humalog is contraindicated during episodes of hypoglycemia and in patients sensitive to Humalog or any of its excipients.

WARNINGS: This human insulin analog differs from regular human insulin by its rapid onset of action as well as a shorter duration of activity. When used as a mealtime insulin, the dose of Humalog should be given within 15 minutes before or immediately after the meal. Because of the short duration of action of Humalog, patients with type 1 diabetes also require a longer-acting insulin to maintain glucose control (except when using an external insulin pump).

External Insulin Pumps: When used in an external insulin pump, Humalog should not be diluted or mixed with any other insulin. Patients should carefully read and follow the external insulin pump manufacturer's instructions and the "PATIENT INFORMATION" leaflet before using Humalog.

Physicians should carefully evaluate information on external insulin pump use in the Humalog physician package insert and in the external insulin pump manufacturer's instructions. If unexplained hyperglycemia or ketosis occurs during external insulin pump use, prompt identification and correction of the cause is necessary. The patient may require interim therapy with subcutaneous insulin injections (see PRECAUTIONS, For Patients Using External Insulin Pumps, and DOSAGE AND ADMINISTRATION).

Hypoglycemia is the most common adverse effect associated with the use of insulins, including Humalog. As with all insulins, the timing of hypoglycemia may differ among various insulin formulations. Glucose monitoring is recommended for all patients with diabetes and is particularly important for patients using an external insulin pump.

Any change of insulin should be made cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type (eg, regular, NPH, analog), species, or method of manufacture may result in the need for a change in dosage.

PRECAUTIONS: General—Hypoglycemia and hypokalemia are among the potential clinical adverse effects associated with the use of all insulins. Because of differences in the action of Humalog and other insulins, care should be taken in patients in whom such potential side effects might be clinically relevant (eg, patients who are fasting, have autonomic neuropathy, or are using potassium-lowering drugs or patients taking drugs sensitive to serum potassium level). Lipodystrophy and hypersensitivity are among other potential clinical adverse effects associated with the use of all insulins.

As with all insulin preparations, the time course of Humalog 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. Insulin requirements may be altered during illness, emotional disturbances, or other stress.

Hypoglycemia—As with all insulin preparations, hypoglycemic reactions may be associated with the administration of Humalog. Rapid changes in serum glucose concentrations may induce symptoms of hypoglycemia in persons with diabetes, regardless of the glucose value. 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.

Renal Impairment—The requirements for insulin may be reduced in patients with renal impairment.

Hepatic Impairment—Although impaired hepatic function does not affect the absorption or disposition of Humalog, careful glucose monitoring and dose adjustments of insulin, including Humalog, may be necessary.

Allergy—Local Allergy—As with any insulin therapy, patients may experience redness, swelling, or itching at the site of injection. These minor reactions usually resolve in a few days to a few weeks. 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—Less common, but potentially more serious, is generalized allergy to insulin, which 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. Localized reactions and generalized myalgias have been reported with the use of cresol as an injectable excipient. In Humalog-controlled clinical trials, pruritus (with or without rash) was seen in 17 patients receiving Humulin R® (N=2969) and 30 patients receiving Humalog (N=2944) (P=.053).

Antibody Production—In large clinical trials, antibodies that cross-react with human insulin and insulin lispro were observed in both Humulin R- and Humalog-treatment groups. As expected, the largest increase in the antibody levels during the 12-month clinical trials was observed with patients new to insulin therapy.

Usage of Humalog in External Insulin Pumps—The infusion set (reservoir syringe, tubing, and catheter), Disetronic® D-TRON®^{2,3} or D-TRONplus®^{2,3} cartridge adapter, and Humalog in the external insulin pump reservoir should be replaced and a new infusion site selected every 48 hours or less. Humalog in the external insulin pump should not be exposed to temperatures above 37°C (98.6°F).

In the D-TRON®^{2,3} or D-TRONplus®^{2,3} pump, Humalog 3 mL cartridges may be used for up to 7 days. However, as with other external insulin pumps, the infusion set should be replaced and a new infusion site should be selected every 48 hours or less.

When used in an external insulin pump, Humalog should not be diluted or mixed with any other insulin (see INDICATIONS AND USAGE, WARNINGS, PRECAUTIONS, For Patients Using External Insulin Pumps, Mixing of Insulins, DOSAGE AND ADMINISTRATION, and Storage).

Information for Patients—Patients should be informed of the potential risks and advantages of Humalog and alternative therapies. Patients should also be informed about the importance of proper insulin storage, injection technique, timing of dosage, adherence to meal planning, regular physical activity, regular blood glucose monitoring, periodic hemoglobin A1C testing, recognition and management of hypoglycemia and hyperglycemia, and periodic assessment for diabetes complications.

Patients should be advised to inform their physician if they are pregnant or intend to become pregnant.

Refer patients to the "PATIENT INFORMATION" leaflet for timing of Humalog dosing (≤15 minutes before or immediately after a meal), storing insulin, and common adverse effects.

For Patients Using Insulin Pen Delivery Devices: Before starting therapy, patients should read the "PATIENT INFORMATION" leaflet that accompanies the drug product and the User Manual that accompanies the delivery device. They should also reread these materials each time the prescription is renewed. Patients should be instructed on how to properly use the delivery device, prime the Pen to a stream of insulin, and properly dispose of needles. Patients should be advised not to share their Pens with others.

For Patients Using External Insulin Pumps: Patients using an external infusion pump should be trained in intensive insulin therapy and in the function of their external insulin pump and pump accessories. Humalog was tested in the MiniMed® Models 506, 507, and 508 insulin pumps using MiniMed® Polyfin®¹ infusion sets. Humalog was also tested in the Disetronic® H-TRONplus® V100 insulin pump (with plastic 3.15 mL insulin reservoir), and the Disetronic D-TRON®^{2,3} and D-TRONplus®^{2,3} insulin pumps (with Humalog 3 mL cartridges) using Disetronic Rapid®² infusion sets.

The infusion set (reservoir syringe, tubing, catheter), D-TRON®^{2,3} or D-TRONplus®^{2,3} cartridge adapter, and Humalog in the external insulin pump reservoir should be replaced, and a new infusion site selected every 48 hours or less. Humalog in the external pump should not be exposed to temperatures above 37°C (98.6°F).

A Humalog 3 mL cartridge used in the D-TRON®^{2,3} or D-TRONplus®^{2,3} pump should be discarded after 7 days, even if it still contains Humalog. Infusion sites that are erythematous, pruritic, or thickened should be reported to medical personnel, and a new site selected.

Humalog should not be diluted or mixed with any other insulin when used in an external insulin pump.

Laboratory Tests—As with all insulins, the therapeutic response to Humalog should be monitored by periodic blood glucose tests. Periodic measurement of hemoglobin A1C is recommended for the monitoring of long-term glycemic control.

Drug Interactions—Insulin requirements may be increased by medications with hyperglycemic activity, such as corticosteroids, isoniazid, certain lipid-lowering drugs (eg, niacin), estrogens, oral contraceptives, phenothiazines, and thyroid replacement therapy (see CLINICAL PHARMACOLOGY).

Insulin requirements may be decreased in the presence of drugs that increase insulin sensitivity or have hypoglycemic activity, such as oral antidiabetic agents, salicylates, sulfa antibiotics, certain antidepressants (monoamine oxidase inhibitors), angiotensin-converting-enzyme inhibitors, angiotensin II receptor blocking agents, beta-adrenergic blockers, inhibitors of pancreatic function (eg, octreotide), and alcohol. Beta-adrenergic blockers may mask the symptoms of hypoglycemia in some patients.

Mixing of Insulins—Care should be taken when mixing all insulins as a change in peak action may occur. The American Diabetes Association warns in its Position Statement on Insulin Administration, "On mixing, physiochemical changes in the mixture may occur (either immediately or over time). As a result, the physiological response to the insulin mixture may differ from that of the injection of the insulins separately." Mixing Humalog with Humulin® N or Humulin® U does not decrease the absorption rate or the total bioavailability of Humalog.