Facilities at Risk When Nurses Violate Standards

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 her medical record. One afternoon, a certified nursing assistant noticed a change in the resident’s status, including a thick white discharge 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 charge nurse repositioned her, at which time blood began streaming from the woman’s nose.

The charge nurse and the RN did not make an incorrect decision. 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

Legal Issues

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.

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Step up to a range of insulin delivery options.
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, lipoatrophy, and hypersensitivity. Systemic allergy is less common, but may be life-threatening. Because of the difference in action of Humalog, care should be taken in patients in whom hypoglycemia or hypokalemia may be clinically relevant (e.g., 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.

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Humulin® is a registered trademark of Eli Lilly and Company.

Janet K. Feldkamp
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 Delaware’s Adult Abuse Registry for violating the nursing standard of care when he failed to perform CPR or call 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 established 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

Continued on following page
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 allergic to Humalog, a recombinant insulin.

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 an aspart 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 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 intervention 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 titration 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, manufacture, type (eg, regular, NPH, analogs), 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 estimating the dose and choosing the new site selected. Such potential side effects might be critically 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 disease.

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, redness, 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 creosol as an injectable excipient. In Humalog-controlled clinical trials, pruritus (with or without rash) was seen in 17 patients receiving Humulin R® (N=2469) and 30 patients receiving Humulin N® (N=2344) (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 pump, 3 mL 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°F). In the D-TRON®2,3 or D-TRONplus®2,3 pump, 3 mL cartridges may be used for up to 7 days. However, as with other external insulin pumps, the insulin cartridge 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 insulins.

DOSAGE AND ADMINISTRATION

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” booklet 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 be informed of how to properly insert the device, prime the Pen to a blood level, check 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 insulin 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 505, 507, and 508 insulin pumps using MiniMed® Payall® infusion sets. Humalog was also tested in the Disetronic® 4H-TRONplus® V100 insulin pump (with plastic 3.15 mL insulin reservoir), and the Disetronic D-TRON®2,3 and D-TRONplus®2,3 external insulin pumps (with 3 mL cartridge) using Disetronic Rapid® 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°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, isorotides, certain lipid-lowering drugs, certain antipsychotics, 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, sulfas antibiotics, certain antidepressants (monooamine oxidase inhibitors), angiotensin-converting-enzyme inhibitors, angiotensin II receptor blocking agents, nonsteroidal anti-inflammatory agents, and alcohol. Beta-adrenergic blockers may mask the symptoms of hypoglycemia in some individuals.

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, physiologic 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 R® or Humulin N® does not decrease the absorption rate or the total bioavailability of Humalog.