

Parental Consent Barrier to Teen Vaccination

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VANCOUVER, B.C. — The inability of older adolescents to provide consent for vaccinations creates a barrier to vaccine delivery, new research suggests.

In a survey of 280 medical providers from 43 states, 95% said that 17-year-olds “sometimes” or “often” present without a parent; 10% reported that this is true for 12-year-olds.

The providers were then asked how likely it was that an unaccompanied minor adolescent in their state would be vaccinated for influenza; combined tetanus, diphtheria, and pertussis (Tdap); and human papillomavirus (HPV) if the vaccines were available for free, the patient was medically eligible, and the parent was not available to consent.

Responses varied by vaccine type, patient age, and clinical setting, said Dr. Carol Ford of the University of North Carolina, Chapel Hill.

If a 17-year-old presented alone for routine care in a private primary care clinic and was due for all three vaccines but a

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parent could not be reached, 30% would not get any of the vaccines. If the same patient presented alone to a private clinic for confidential services, 40% would not get vaccinated, Dr. Ford reported.

If the unaccompanied minor was 12 years old, 50% would not get influenza or Tdap, and 70% would not get the HPV vaccine, according to the survey.

In a public primary care setting, approximately half of 17-year-olds presenting for routine care and 65% of 12-year-olds would not get any vaccines if unaccompanied by a parent, she noted.

Between 30% and 50% of health care provider respondents said that an adolescent presenting to a public clinic for confidential services would not get the HPV vaccine and 60%-70% would not get Tdap or influenza vaccines, with variation by age, Dr. Ford said.

“We still have to think hard about how to get all teens vaccinated, but I think that this study really highlights the fact that there are a lot of missed opportunities among these older teens,” she said in an interview.

Interventions to increase adolescent vaccinations include strategies such as anticipatory consent for vaccinations at the time of school physical examinations; advance consent for additional doses, as with the three-dose HPV vaccine; and calling parents on cell phones.

Providers must work within the context of legal, ethical, and professional

guidelines regarding minor consent, but hospitals have a great deal of variety and flexibility regarding the process of documenting consent, Dr. Ford said.

Federal law requires that all health care providers give vaccine information statements to parents or patients before administering each dose of the vaccines listed in the 2010 vaccine schedule.

The American Academy of Pediatrics believes that physicians have an ethical

and legal obligation in most cases to obtain parental permission to undertake recommended medical interventions, and that in many circumstances they should also solicit patient assent when developmentally appropriate (Pediatrics 1995;95:314-7). The AAP also notes that physicians should seek informed consent directly from patients in cases involving emancipated or mature minors with adequate decision-making capacity,

or when otherwise permitted by law.

During a discussion of the study, it was noted that most states require patient assent, not consent. Survey respondents would support efforts to allow minors to consent for vaccination at a mean of 14.26 years for Tdap, 14.08 years for influenza, and 13.81 for HPV, Dr. Ford said. ■

Disclosures: Dr. Ford reported that she had no disclosures.

If you think all basal insulins are the same, think again

The topic of insulin and cancer has garnered increased attention with the publication of 4 retrospective studies in *Diabetologia* that investigate the potential role of a specific basal insulin analog in cancer risk.¹⁻⁴

For decades, researchers have investigated the relationship between insulin and IGF-1 receptor activation and the development of certain cancers.⁵ To date, the clinical significance of the in vitro activity of IGF-1R has not been established.

The Novo Nordisk philosophy of engineering insulin and IGF-1R affinity

Novo Nordisk has been working on refining the attributes of insulin for more than 85 years, redesigning the insulin molecule with a focus on efficacy and safety.

We have developed insulin analogs that work like normal human insulin but which have a more consistent and predictable absorption profile associated with a low risk of hypoglycemia, the most common adverse event with insulin use.⁶⁻⁸

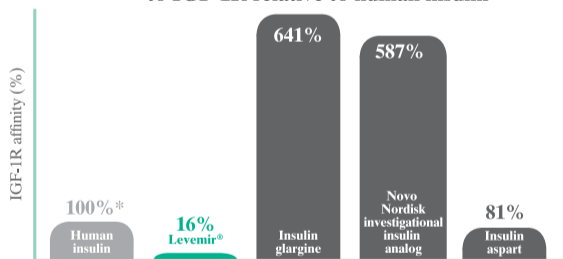
In 1992, Novo Nordisk stopped development of a rapid-acting investigational insulin analog when laboratory testing revealed it had undesirable mitogenic side-effects.⁹ A toxicopharmacological evaluation indicated the compound's affinity to IGF-1R was high, one possible cause of the tumor growth.⁹

With work on this investigational compound discontinued, Novo Nordisk adopted a philosophy that all future insulins cannot have a greater binding affinity to IGF-1R and the insulin receptor (IR) than human insulin, the relevant comparator against which binding affinity is measured.⁹

Levemir® was designed with a low affinity to IGF-1R

Levemir® was designed with the lessons of the earlier investigational insulin analog in mind, with a specific fatty acid side chain to LysB29 to prolong its absorption and provide steady plasma levels while also having a lower IGF-1R affinity than human insulin.¹⁰

Levemir® was shown to have a low affinity to IGF-1R relative to human insulin¹⁰



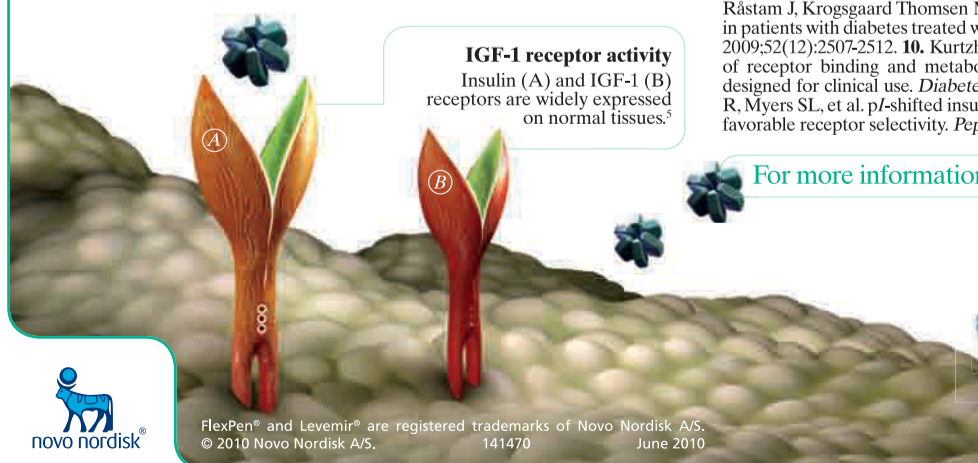
*Human insulin is the relevant comparator against which IGF-1R affinity was measured.

An in vitro study that compared the insulin- and IGF-1R-binding properties and the metabolic and mitogenic potencies of the rapid-acting and long-acting insulin analogs with human insulin. IGF-1R affinity was measured using purified human IGF-1R.¹⁰

In another study, conducted by Lilly Research Laboratories, insulin glargine had an affinity to IGF-1R of 551% compared with 100% for human insulin.¹¹

The clinical significance of the in vitro activity of IGF-1R has not been established.

IGF-1 receptor activity
Insulin (A) and IGF-1 (B) receptors are widely expressed on normal tissues.⁵



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.

Levemir® should not be diluted or mixed with any other insulin preparations.

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 antidiabetic treatment may require adjustment.

Needles and Levemir® FlexPen® must not be shared.

Inadequate dosing or discontinuation of treatment may lead to hyperglycemia and, in patients with type 1 diabetes, diabetic ketoacidosis. 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. Less common but more serious are severe cases of generalized allergy, including anaphylactic reaction, which may be life threatening.

Please see brief summary of Prescribing Information on adjacent page.

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For more information, visit www.IGF1Raffinity.com



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Levemir®
insulin detemir (rDNA origin) injection