

## Macrosomia Drops With CGM Use

BY SARA FREEMAN  
Contributing Writer

ROME — Continuous glucose monitoring during pregnancy was linked to a significant reduction in median birth weight and macrosomia risk in a study of 71 women with type 1 or type 2 diabetes.

The randomized, open study also showed that pregnant women who wore the monitors for 5-7 days, at 4-6 weekly intervals, had better blood glucose control than did women who received standard prenatal care alone.

The study comprised 46 women with type 1 and 25 women with type 2 diabetes. A total of 38 women were randomized to use continuous glucose monitoring (CGM) as an educational tool to inform decision making and future therapeutic changes;



**Children in the continuous glucose monitoring group had a 64% lower risk of macrosomia.**

DR. MURPHY

the remaining 33 women were randomized to standard care, study investigator Dr. Helen R. Murphy reported Sept. 8 at the annual meeting of the European Association for the Study of Diabetes.

All statistical analyses were performed on an intention-to-treat basis, said Dr. Murphy of Ipswich (England) Hospital.

At weeks 32-36 of gestation, hemoglobin A<sub>1c</sub> levels were significantly lower in the CGM group than in the standard care group (5.8% vs. 6.4%).

In addition, infants born to women in the CGM group were significantly less likely to have a high birth weight than were those born to women in the standard care group. The mean standard deviation (SD) score for birth weight was 0.9 for infants in the CGM group and 1.6 for those in the standard care group.

“What is even more striking is the complete absence of small-for-gestational age babies in women randomized to standard antenatal care,” Dr. Murphy said.

She also noted that there were two infants that had SD scores of above three in the CGM arm, but their mothers had withdrawn from the study before completion.

Compared with children in the standard care arm, the children in the CGM group were at decreased risk (odds ratio 0.36) of macrosomia, defined as a birth weight in the 90th percentile or higher.

CGM was well accepted by the women, according to Dr. Murphy, adding that they wore the monitors on their flank at least once a trimester. The monitors were provided free of charge by Medtronic UK. Ipswich Hospital Diabetes Centre Charity Research Fund and Diabetes UK supported the investigator-led study. ■

## Prepregnancy Diabetes Ups Defect Risk

BY HEIDI SPLETE  
Senior Writer

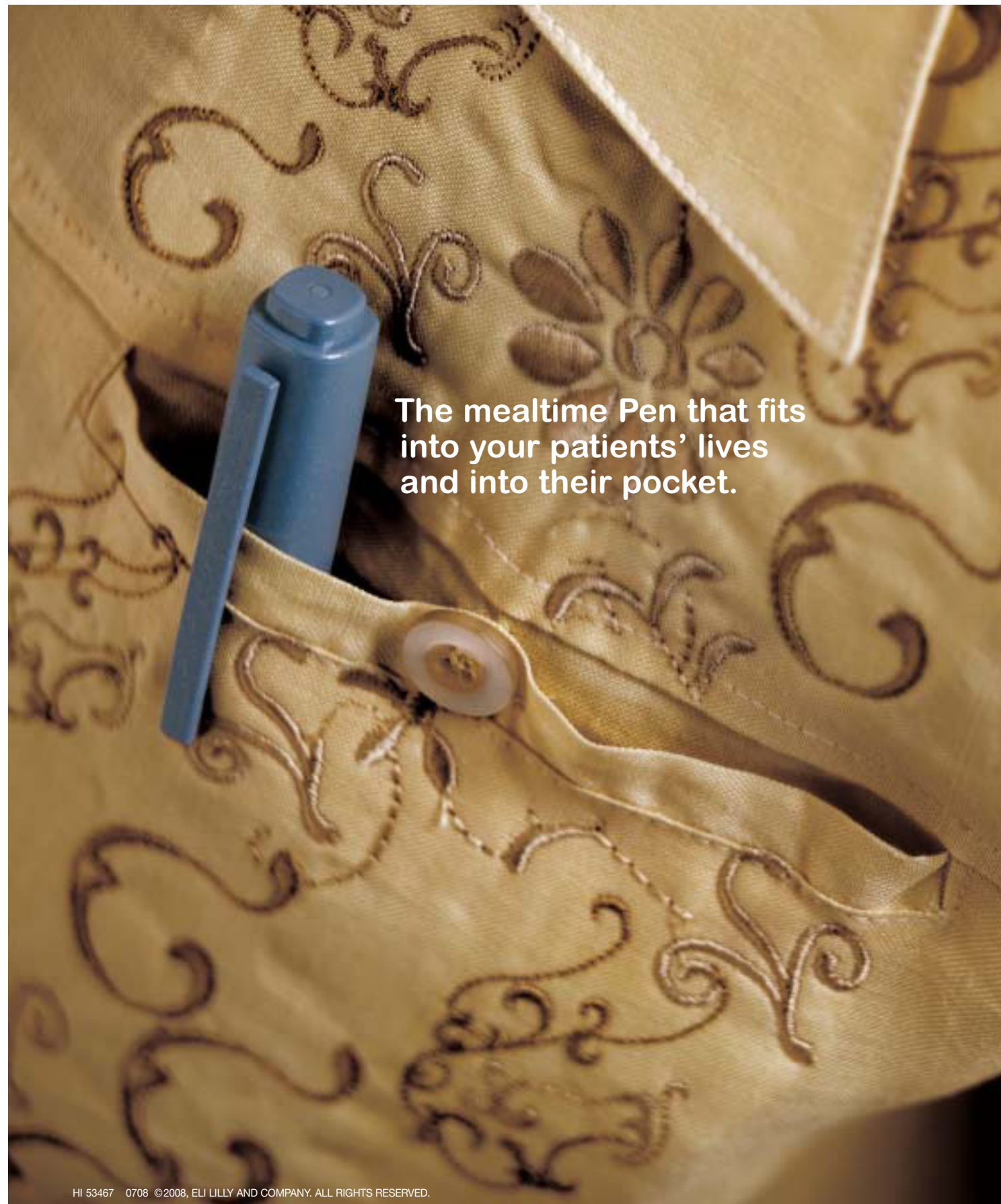
**W**omen who are diagnosed with diabetes prior to pregnancy are three to four times more likely to have a child with birth defects, compared with women who don't have diabetes prior to pregnancy, based on results from a study of more than 15,000 live births published online in the American Journal of Obstetrics and Gynecology.

Although previous studies have established pregestational diabetes mellitus (PGDM) as a risk factor for several types of birth defects, the prevalence of maternal diabetes in cases of birth defects has not been well quantified, said Dr. Adolfo Correa, an epidemiologist at the Centers for Disease Control and Prevention.

Dr. Correa and his colleagues reviewed data from 13,030 cases of infants with birth defects and 4,895 control infants. The data came from the National Birth

Defects Prevention Study, an ongoing population-based study that includes birth defect surveillance at 10 locations in the United States (Am. J. Obstet. Gynecol. 2008 [doi:10.1016/j.ajog.2008.06.028]).

The overall prevalence of PGDM was 2.2% in cases of infants with birth defects (283 cases/13,030 births), compared with 0.5% for the control infants (24 cases/4,895 births). In the birth defects group, 138 mothers had type 1 diabetes and 145 had type 2 diabetes. In the con-



**The mealtime Pen that fits into your patients' lives and into their pocket.**

tol group, 10 mothers had type 1 diabetes and 14 had type 2 diabetes.

Overall, 70% of the cases of isolated birth defects and 90% of cases of multiple birth defects in infants whose mothers had PGDM might be attributed to the mother's diabetes, the researchers noted. The prevalence of both types of diabetes was highest among mothers of infants with multiple defects.

The researchers found significant associations between PGDM and several types of heart defects including aortic stenosis and atrial ventricular septal defects. They also found significant associations between PGDM and other types of birth defects in-

cluding hydrocephalus, cleft lip (with and without cleft palate), anorectal atresia, and longitudinal limb deficiencies. The associations between PGDM and these defects were seen in isolated cases, but the association was even stronger in cases of multiple defects.

"Our findings of moderate to strong odds ratios for PGDM and a wide range of birth defects are consistent with and expand on previous reports that examined all birth defects as a group or broad categories of birth defects," the researchers said.

The study population included women with known diabetes status prior to pregnancy and delivery dates between Oct. 1,

1997, and Dec. 31, 2003. The researchers excluded cases of birth defects that were linked to a known cause, such as a genetic disorder.

In addition, the prevalence of gestational diabetes mellitus (GDM) was 3.7% among control mothers vs. 5.1% among mothers whose infants had birth defects. But some women who are diagnosed with gestational diabetes may in fact have had undiagnosed type 2 diabetes prior to pregnancy, the researchers noted. "We were able to identify overweight and obese women with GDM as a subgroup who may be at increased risk of having offspring with birth defects and in need of

closer follow-up examination and evaluation," they wrote.

The study was limited by the use of maternal self-reports of diagnosed diabetes and by a lack of data on how many pregnancies complicated by PGDM were terminated in the study population.

More research is needed to determine how maternal hyperglycemia affects the developing fetus, the researchers noted. But the range and severity of the defects suggest that diabetes affects the developing embryo in complex and nonspecific ways, they added.

Dr. Correa stated that he had no financial conflicts to disclose. ■

## Humalog® KwikPen®

The easy-to-use, easy-to-inject prefilled pen.\*<sup>1</sup>

- Small, lightweight, and portable
- Allows your patients to discreetly deliver Humalog®
- Does not need refrigeration after first use
- Easy to set the dose<sup>1</sup>
- Short thumb-reach at high doses

(Actual size)



### Please note:

When prescribing Humalog KwikPen, you will need to write a separate prescription for BD needles.

*Humalog* KwikPen®

insulin lispro injection (rDNA origin)

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.

### Important Safety Information

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.

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

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

### 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 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).

**For additional safety profile and other important prescribing considerations, see the accompanying Brief Summary of full Prescribing Information.**

**Please see full user manual that accompanies the Pen.**

Humalog® is a registered trademark of Eli Lilly and Company. Humalog is available by prescription only.

Humalog® KwikPen® is a registered trademark of Eli Lilly and Company. Humalog KwikPen is available by prescription only.

\* KwikPen Design Validation User Study included adult male and female participants with type 1 and type 2 diabetes. Of the total 150 study participants, 56 were insulin-naïve, 42 were currently administering insulin with a vial and syringe, and 52 were experienced insulin pen users.

### Reference

1. Data on file, Eli Lilly and Company. KwikPen Design Validation User Study. HUM20071024A.

### Also Available

Original  
Prefilled Pen



Humalog® is also available by prescription in the **original Humalog Prefilled Pen.**

Find out more at [www.humalog.com](http://www.humalog.com)



Humanly possible.

*Humalog*

insulin lispro injection (rDNA origin)

*Lilly*