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STUDY CONFIRMS THAT SIGNIFICANT INSULIN DOSE ERRORS CAN RESULT WHEN BLOOD GLUCOSE METERS ARE MISCODED

Findings Published in Journal of Diabetes Science and Technology

Accurate Coding is Key to Preventing Potentially Serious Health Complications Associated with Errors in Insulin Dosing

Tarrytown, NY (March 1, 2007) – When persons with diabetes use miscoded blood glucose meters to determine how much insulin to take, significant errors in insulin dose can result that may potentially lead to short- and long-term health complications, according to findings of a new study just published in the *Journal of Diabetes Science and Technology* (www.journalofdst.org).

The study findings also showed that meters with No Coding™ technology (meters that automatically set the correct code anytime a test strip is inserted) gave superior performance over meters used in this study that had been correctly coded manually. This also translated into a lower probability of insulin dose error.

The American Diabetes Association estimates that there are 14.6 million children and adults diagnosed with diabetes in the United States[1], of which an estimated 4.4 million, or 30%, require insulin to manage their disease[2]. Those who require insulin must closely monitor their blood sugar with a blood glucose meter to plan their meals, exercise regimens and insulin dosage.

In this study, using the low dose insulin algorithm, for certain miscoded blood glucose meters, the probability of insulin error of plus or minus 2 units of insulin could be as high as 50% as compared to 7.1% for correctly, manually coded meters. The probability of insulin dose error of plus or minus 3 units of insulin could be as high as 22.3% for the miscoded meters but only 0.49% for the correctly, manually coded meters.

For the meters that do not require manual coding, the probability of plus or minus 1 unit and plus or minus 2 units of insulin could be as high as 35.4% and 1.4% respectively. There were no calculated insulin dose errors above plus or minus 2 units with the meters that do not require manual coding.

Coding is the process by which a blood glucose meter is matched to each new box of test strips being used. This is done either by inserting a code strip or code chip into the meter, or by entering a code number into the meter. If this step is not performed, the meter may give inaccurate results, which may lead to wrong therapy. For example, relying on a miscoded blood glucose meter to determine how much insulin to take can result in a potentially harmful overdose. Insulin overdose may cause dangerously low blood sugar (hypoglycemia) leading to behavioral changes, confusion, loss of consciousness and, if untreated, seizure, coma and even death. Chronic underdosing of insulin may contribute to the long-term health problems associated with high blood sugar including kidney disease, nerve disease, eye problems, and heart disease.

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News Release

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"When dealing with patients with diabetes we've observed that many either do not understand what proper coding is, or do not realize its importance. Patients sometimes use expired test strips and/or do not properly code their blood glucose meters to the lot of test strips they are using," said Dr. Steven Edelman, an author on the study, and Professor of Medicine, division of Endocrinology and Metabolism, University of California, San Diego, and the Veterans Affairs Medical Center and founder of TAKING CONTROL OF YOUR DIABETES (www.tcoyd.org).

"This is significant because a previous study I conducted found that approximately 16% – or one out of six – persons failed to properly manually code their blood glucose meters to the lot of test strips being used[3]," said Dr. Charles H. Raine, III, also an author on the newly published study and Director, Diabetes Control and Endocrinology Center, Orangeburg, South Carolina. "Understanding the potentially serious consequences of relying on a meter that is not properly coded - is essential for every person with diabetes, especially those who need to take insulin," he added.

The study authors concluded that to avoid insulin dosing errors, people should be carefully instructed how to correctly code their meters or be advised to use a blood glucose meter that does not require manual coding.

Study Design
The study involved 116 patients at three clinical centers. The blood glucose values for patients in this study ranged from 52 – 498 mg/dL. After fasting, the patients were given a two-hour meal tolerance test. At zero, 60 and 120 minutes the study subjects' fingerstick blood was tested on five different popular blood glucose meters (two were meters with No Coding™ technology).

Some of the meters that do require coding were purposely miscoded to the lot of test strips. The meters with No Coding™ technology were always properly coded due to their inherent design. The values from all the meters were compared with blood glucose values measured on a laboratory glucose analyzer to determine how accurate (inaccurate) the meters were.

Glucose values obtained from some of the miscoded meters used for this study showed an average error ranging between plus 29% and minus 37%.
Using the blood glucose values from these meters along with three insulin dose algorithms, Monte Carlo simulations, (a statistical method that uses existing data sets to forecast performance in the field) were conducted on the data from the clinical trial to generate 'ideal' and 'simulated-meter' glucose values, and subsequent probability of insulin dose errors based on normal and empirical distribution assumptions. This simulation was based on various assumptions such as, one unit (1U) of insulin covers 50mg/dL blood glucose* (low dose algorithm). From these calculations, the probability of insulin dose errors for the three types of blood glucose meters (miscoded, manually correctly coded and those that do not require coding) were determined.

The probability for an error of plus or minus one unit of insulin using the low dose algorithm was as high as 44.6% for correctly, manually coded meters compared to 49.6% for incorrectly coded meters. The probability for an error with a miscoded meter of ± four units of insulin was as high as 1.4% and for ± five units of insulin was as high as 0.04%. There was no instance of a ± four or five unit error with correctly, manually coded meters using the low dose algorithm. For meters that do not require coding there were no calculated insulin dose errors above ± two units. Results using empirical distributions showed similar trends of insulin dose errors.

Bayer HealthCare, Diabetes Care

Bayer HealthCare, Diabetes Care is a worldwide leader in diabetes, supporting customers in 100 countries. Since the introduction of CLINITEST® reagent tablets in 1941, Bayer has led the way in diabetes care product innovation. The company changed the face of diabetes care in 1969 when it introduced the first portable blood glucose meter and test strips. Bayer HealthCare further innovated diabetes management by being the first company to introduce a suite of blood glucose monitors with No Coding™ technology. The BREEZE® and CONTOUR® blood glucose monitoring systems offer people with diabetes an unparalleled choice in diabetes management systems. The Arthritis Foundation in the United States and the Arthritis Society of Canada each granted Ease-of Use Commendation to the BREEZE meter, representing the first time a blood glucose meter has been recognized as easy to use for arthritis sufferers.

In July 2006, Bayer Diabetes Care acquired Metrika Inc., maker and manufacturer of A1CNow+®, a meter-based diabetes monitoring system for measurement of HbA1c (glycated hemoglobin) an important indicator of long term blood sugar control.

Bayer HealthCare, Diabetes Care global headquarters is located in Tarrytown, New York, in the United States and operates as part of Bayer HealthCare LLC, a member of the worldwide Bayer HealthCare group.

Bayer HealthCare

Bayer HealthCare, a subsidiary of Bayer AG, is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Diabetes Care and Pharmaceuticals divisions. The pharmaceuticals business operates under the name Bayer Schering Pharma AG. Bayer HealthCare's aim is to discover and manufacture products that will improve human and animal health worldwide.

** Small variations may occur due to the nature of Monte Carlo simulation.*

1 American Diabetes Association: www.diabetes.org/diabetes-statistics.jsp
2 Roper 2005 U.S. Diabetes Patient Marker Study, April 19, 2006
3 Raine, C.H. Endo Prac 9: pg 137, 2003

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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