

Diabetes Fact Sheet

Diabetes is a serious, lifelong condition that is associated with long-term complications such as blindness, heart and blood vessel disease, stroke, kidney failure, amputations and nerve damage. An estimated 26.8 million people in the United States have diabetes today.¹ The disease affects 246 million people worldwide and is expected to affect 380 million by the year 2025.²

Diabetes & the early insulin response

- Diabetes is a metabolic disorder characterized by the body's inability to properly use the foods we eat for growth and energy. The main source of energy in our bodies comes from food that is broken down into glucose, a form of sugar in the blood. Glucose, with the help of insulin, passes from the blood and enters the body's cells to supply them with energy.
- Insulin, a hormone produced by beta cells in the pancreas, normally regulates the body's glucose levels, but in people with diabetes, insufficient levels of insulin are produced (type 1 diabetes), or the body fails to respond adequately to the insulin it produces (type 2 diabetes). The result is an abnormally high build-up of glucose in the blood, a condition called hyperglycemia.
 - Following a meal, insulin is rapidly released from the pancreas' beta cells. This is known as the early insulin response.³ Normally, the early insulin response then quickly "switches off" the liver's production of glucose, thus preventing its build-up in the blood.
 - In patients with diabetes, there is a loss of the early insulin response resulting in an inadequate suppression of glucose production, which is a major cause of post-mealtime (prandial) hyperglycemia.
 - Early signs of hyperglycemia include increased thirst, headaches, difficulty concentrating, blurred vision, frequent urination, fatigue and weight loss.⁴ Left untreated, hyperglycemia can lead to damaged nerves, blood vessels and other body organs.
 - The rapid actions of the early insulin response are critical for the prevention of postprandial hyperglycemia.
 - The loss of the early insulin response is a defect found in patients with type 1 and type 2 diabetes.
 - Restoring the early insulin response is the goal for improving postprandial glucose tolerance.

¹ "Country Summary Table." International Diabetes Federation Diabetes Atlas. Available at: <http://www.diabetesatlas.org/content/country-summary-table> Accessed on 12/16/09.

² "Did You Know?" International Diabetes Federation. Available at: <http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A> Accessed on 4/21/09.

³ "Insulin Resistance, Impaired Early Insulin Response, and Insulin Propeptides as Predictors of the Development of Type 2 Diabetes." DiabetesCare. Available at:

<http://www.google.com/url?sa=t&source=web&ct=res&cd=1&url=http%3A%2F%2Fcare.diabetesjournals.org%2Fcgi%2Fcontent%2Fabstract%2F27%2F6%2F1433&ei=InnwSfmfH87gtgeq3aHFDw&usg=AFQjCNEzzWf8sYePNMCS00uqycmgQ5CjjA> Accessed on 4/21/09.

⁴ "Hyperglycemia." MedicineNet.com. Available at: <http://www.medicinenet.com/hyperglycemia/page2.htm> Accessed on 4/21/09.

- The primary treatment for type 1 diabetes is daily intensive insulin therapy. When patients with type 2 diabetes are first diagnosed, the initial therapy, according to ADA/EASD guidelines, is typically lifestyle modifications and an oral agent called metformin, but ultimately many patients with type 2 diabetes will require insulin therapy in order to maintain appropriate levels of blood glucose.⁵

Unmet need in insulin therapy

- Many patients with diabetes, including those on insulin therapy, are not achieving their target A1C levels, a measure of a person's average blood sugar levels.⁶
- Over time, the beta cells in the pancreas lose their ability to produce insulin, and a person's A1C levels steadily rise despite anti-diabetic therapy.
- All currently available injectable insulins are slowly absorbed and therefore do not mimic the rapid actions of the normal early insulin response. As a consequence, patients do not have adequate levels of insulin present at the initiation of a meal and tend to be over-insulinized between meals. This delay in insulin delivery results in hyperglycemia early after a meal, followed by a tendency for hypoglycemia (unhealthy low levels of glucose) to develop between meals. To offset these ongoing fluctuations in blood glucose levels, patients may snack between meals.
 - In addition to the fear of hypoglycemia, one of the major barriers to the appropriate initiation and use of insulin is the fear patients have of gaining weight due to the between-meal snacks that must be eaten to manage ongoing fluctuations in blood glucose levels.⁷
- Multiple factors contribute to the slow absorption of injectable insulins, including the need for the large insulin molecules (hexamers) to break down into a biologically active form of insulin (monomers).
- The slow absorption of injectable insulins results in a slow onset of action, a delayed time to peak insulin levels and a prolonged duration of action that can raise the potential for developing hypoglycemia.
- The diabetes community has an unmet need for insulin therapy that closely mimics the early insulin response and optimally controls postprandial hyperglycemia while minimizing the risk of hypoglycemia.

⁵ "New EASD/ADA Consensus Recommends Metformin at Diagnosis of Type 2 Diabetes." DocGuide.com. Available at: <http://www.docguide.com/dg.nsf/c199ac7acbf21b1b852565f30052a091/24f189e0ecd35a1f852571e8004ae2b8?OpenDocument> Accessed on 4/21/09.

⁶ "National Diabetes Call to Action and Blueprint for Change." Buston-Marsteller.com. Available at: http://www.burson-marsteller.com/Innovation_and_insights/Case_Studies/Lists/CaseStudies/DispForm.aspx?ID=59&nodeName=Healthcare&subTitle=National%20Diabetes%20Call%20to%20Action%20and%20Blueprint%20for%20Change Accessed on 4/21/09.

⁷ "Insulin Treatment and the Problem of Weight Gain in Type 2 Diabetes." Sage Journals Online. Available at: <http://tde.sagepub.com/cgi/content/abstract/32/6/910> Accessed on 4/21/09.