

What is diabetes?

Diabetes is a chronic medical condition marked by high levels of blood glucose (a form of sugar) resulting from defects in insulin production, insulin action, or both. There are several types of diabetes: type 1 diabetes, type 2 diabetes, gestational diabetes, and pre-diabetes. Diabetes is the leading cause of blindness, amputations, and kidney failure, and is a major contributor to heart attacks and strokes. Overall, the risk for death among people with diabetes is about twice that of people of similar age without diabetes. Diabetes reduces life expectancy by 18 years if diagnosed at age 20, 14 years if diagnosed at age 40, and 10 years if diagnosed at age 60.

Type 1 diabetes

Type 1 diabetes, previously known as juvenile diabetes, is an autoimmune disease in which the body does not produce the hormone insulin. There is no known way to prevent type 1 diabetes.

Type 2 diabetes

Type 2 diabetes, previously known as adult-onset diabetes, is a metabolic disease in which the body does not make enough insulin or use it effectively. Type 2 diabetes can be prevented or delayed by maintaining a healthy weight and exercising regularly.

Gestational diabetes

Gestational diabetes occurs in pregnant women who have never had diabetes before but have higher than normal blood glucose levels during pregnancy. Without intervention, women with gestational diabetes have a 40-60 percent chance of developing type 2 diabetes within 5-10 years.

Pre-diabetes

Pre-diabetes is a condition that raises the risk of developing type 2 diabetes, heart disease and stroke. People with pre-diabetes have blood glucose levels higher than normal but not high enough to be classified as diabetes. Without intervention, about 25 percent of people with pre-diabetes will develop diabetes within three to five years.

Diabetes often goes undiagnosed because many of its symptoms seem so harmless.

Source: California Department of Health

Diabetes in California

Diabetes affects 25.8 million people, or about 8 percent of the U.S. population. It is the seventh leading cause of death and a leading cause of blindness, kidney failure, and amputations. It is also a significant contributor to heart attacks and strokes. Type 2 diabetes is the most common form of the disease, affecting between 90 percent and 95 percent of the 24 million people in the United States with diabetes. Research indicates that obstructive sleep apnea and type 2 diabetes are two prevalent medical conditions with significant associated morbidity and mortality. Besides making it difficult to sleep, sleep apnea increases stress on the body, causing blood sugar levels to rise.

In California, diabetes numbers are escalating. There were an estimated 4 million Californians with diabetes in 2009, or one out of seven adults in the state. Of these, 2.5 million are aware that they have diabetes, and 1.4 million adults are undiagnosed. And the prevalence is rising. From 2000 to 2009, California adults with diagnosed diabetes rose from 6.8 percent to 9.1 percent. Costs in California exceed \$24 billion a year. Direct medical costs (hospitalizations, medical care and treatment supplies) account for about \$18.7 billion with the other \$5.8 billion attributed to indirect costs, such as disability payments, time lost from work, and premature death.

California is on the cutting edge of development of new methods for diagnosing, treating and preventing this highly prevalent disease. All of these methods require substantial research and development, backed by government investments, patient advocacy research groups, corporate venture funding, and traditional venture capital dollars to produce safe and effective patient treatments.

FDA Pilot Program Aims to Deepen Collaborations with Innovators

On April 9, 2012, the FDA's Center for Devices and Radiological Health (CDRH) launched its second version of the Innovation Pathway, or Innovation Pathway 2.0.

The program offers new and modified tools and methods to deepen collaboration between the FDA and innovators early in the process, prior to pre-market submission, with the goal of making the regulatory process more efficient and timely. Two California-based programs were recently selected to participate in its end-stage renal disease (ESRD) initiative. The most common causes of ESRD in the U.S. are diabetes and high blood pressure. The FDA said it chose this particular disease because more than half a million Americans suffer from it. Medicare alone covers some 75 percent of ESRD healthcare costs, which, in 2009, topped \$29 billion.

CHI member University of California, San Francisco will lead an artificial kidney project targeted for clinical trials in 2017. The goal is to create an implantable device that would enable patients with chronic kidney failure to lead healthier and more productive lives without external dialysis or immune suppressant medication.

The other California project, led by Blood Purification Technologies Inc. of Beverly Hills, involves a wearable artificial kidney. A wearable kidney would mimic the function of the kidneys by providing continued dialysis.

Complications of Diabetes in the U.S.

Heart disease and stroke

- In 2004, heart disease was noted on 68 percent of diabetes-related death certificates among people aged 65 years or older.
- In 2004, stroke was noted on 16 percent of diabetes-related death certificates among people aged 65 years or older.
- Adults with diabetes have heart disease death rates about two to four times higher than adults without diabetes.
- The risk for stroke is two to four times higher among people with diabetes.

Hypertension

- From 2005–2008, of adults aged 20 years or older with self-reported diabetes, 67 percent had blood pressure greater than or equal to 140/90 millimeters of mercury (mmHg) or used prescription medications for hypertension.

Blindness and eye problems

- Diabetes is the leading cause of new cases of blindness among adults aged 20–74 years.
- In 2005–2008, 4.2 million (28.5 percent) people with diabetes aged 40 years or older had diabetic retinopathy, and of these, 655,000 (4.4 percent of those with diabetes) had advanced diabetic retinopathy that could lead to severe vision loss.

Kidney disease

- Diabetes is the leading cause of kidney failure, accounting for 44 percent of all new cases of kidney failure in 2008.
- In 2008, 48,374 people with diabetes began treatment for end-stage kidney disease.
- In 2008, a total of 202,290 people with end-stage kidney disease due to diabetes were living on chronic dialysis or with a kidney transplant.

Nervous system disease

- About 60 percent to 70 percent of people with diabetes have mild to severe forms of nervous system damage. The results of such damage include impaired sensation or pain in the feet or hands, slowed digestion of food in the stomach, carpal tunnel syndrome, erectile dysfunction, or other nerve problems.
- Almost 30 percent of people with diabetes aged 40 years or older have impaired sensation in the feet (i.e., at least one area that lacks feeling).
- Severe forms of diabetic nerve disease are a major contributing cause of lower-extremity amputations.

Amputations

- More than 60 percent of nontraumatic lower-limb amputations occur in people with diabetes.
- In 2006, about 65,700 nontraumatic lower-limb amputations were performed in people with diabetes.

PATIENT PROFILE: KELLA SMITH



Kella Smith

For Kella Smith, July 25, 1983 was a fateful day that changed her life forever. She was only six years old when she was diagnosed with type 1 diabetes.

For 17 years, she managed her disease with insulin injections—before meals and bedtime. That’s more than 24,820 injections. The shots hurt and they didn’t give Kella the glucose control she needed to stay healthy. Waking up with high glucose levels every day became exhausting and she simply wanted to live a more normal life.

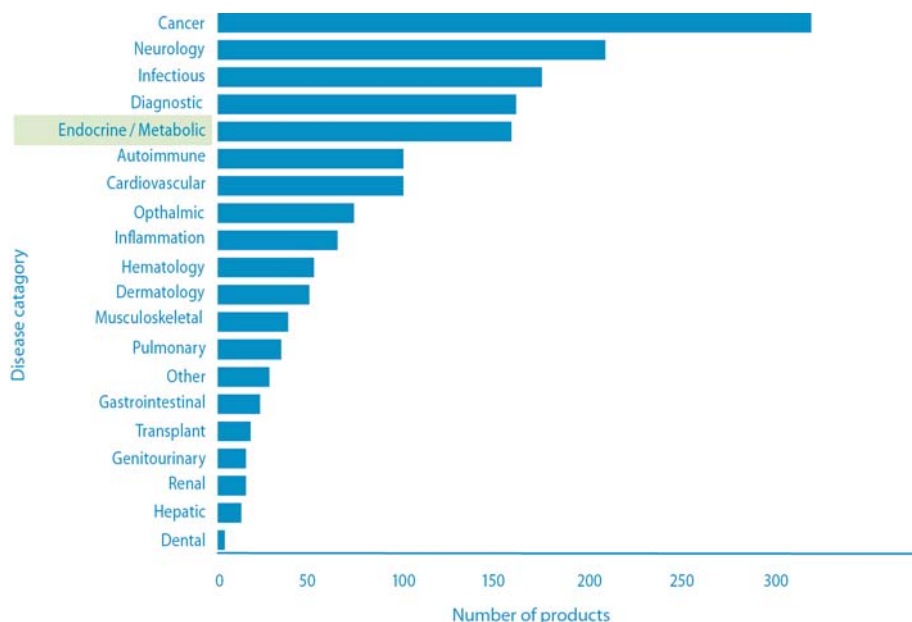
Kella’s life changed dramatically when she began using a Medtronic insulin pump. She immediately experienced freedom and flexibility. She could eat

what she wanted—when she wanted—and could deliver insulin by touching a few buttons on her insulin pump. As Kella’s glucose control improved, she felt better and healthier. But it wasn’t until she added continuous glucose monitoring that she was able to get the control she wanted.

Today, Kella enjoys playing co-ed softball, walking her dog, and traveling whenever she can, which was nearly impossible while on shots. In fact, Kella traveled to India on her own because of her confidence in her insulin pump. A highlight of her trip was seeing the Taj Mahal.

By viewing her glucose trends in real-time, she can make proactive management decisions before her glucose becomes harmful. Kella feels this cutting-edge technology helps her live her life to the fullest and that it’s the next best thing to a cure for diabetes.

California Companies Are Developing Pipeline Products For The Full Spectrum Of Indications



Source: BCIQ: BioCentury Online Intelligence

ADVANCES IN DIABETES DIAGNOSIS AND TREATMENT

Basic Research Roundup

Using human pancreatic tissue, researchers with the **La Jolla Institute for Allergy & Immunology** in San Diego have proven for the first time that certain T cells trigger destruction in the pancreas, which eventually leads to type 1 diabetes. Previously, it was only proven in laboratory dishes and mouse models. The study, which appeared in the January 2, 2012 issue of *The Journal of Experimental Medicine*, examined pancreatic tissue from 45 organ donors who had type 1 diabetes. The lead investigator, Dr. Matthias von Herrath, and his research team were able to detect evidence of the dangerous actions of the CD8 T cells in the pancreatic islets (which contain beta cells).

The Department of Pediatric Endocrinology at **Stanford University** is committed to the development of an artificial pancreas. It is currently receiving grant support from the Juvenile Diabetes Foundation to pursue this goal. The team is working with engineers at UC Santa Barbara and the Rensselaer Institute to develop algorithms for the artificial pancreas. It is also conducting clinical trials with Dr. Peter Chase at the Barbara Davis Center in Colorado to prevent nocturnal hypoglycemia using an artificial pancreas.

The **Special Statutory Funding Program for Type 1 Diabetes Research** is a special appropriation that the National Institute of Diabetes and Digestive and Kidney Diseases administers on behalf of the Secretary of the Department of Health and Human Services, in collaboration with multiple NIH Institutes and Centers and the CDC, for research on the prevention and cure of type 1 diabetes in the amount of \$1.89 billion for fiscal year 1998 through 2013. The program has enabled the creation of unique, innovative, and collaborative research consortia and clinical trials networks focused on the prevention, treatment, and cure of type 1 diabetes.

California Centers of Excellence

At the **Cedars-Sinai Diabetes and Obesity Research Institute**, Richard Nathan Bergman, Ph.D., and his team of researchers are examining the relationship between sleep patterns and diabetes, as well as mechanisms by which bariatric surgery reduces or even eliminates the diabetic condition. The overarching goals of the Institute are to examine the prediction, prevention, treatment

and cure of diabetes, obesity, and associated conditions. Other areas of research include the mechanisms of insulin resistance, the consequences of abdominal obesity, the metabolic effects of psychotropic medications, and the use of mathematical modeling techniques to corroborate genetic loci which contribute risk for diabetes development. The Institute will play a role as a nexus for translational collaboration among the departments of Biomedical Sciences and Medicine, the Imaging Center, the Center for Hypertension Research, and the Department of Surgery, as their ongoing research relates to diabetes and obesity.

City of Hope has a long and impressive history of groundbreaking discoveries in the field of diabetes, spanning over four decades of intense investigation. City of Hope's Division of Diabetes, Endocrinology & Metabolism is also renowned for its islet cell transplantation program, which offers an increasingly viable treatment option for type 1 diabetes. Additionally, City of Hope's Dr. Fouad Kandeel and his team of researchers are collaborating with Medtronic and Juvenile Diabetes Research Foundation to develop an artificial pancreas to put a stop to the never-ending need to check blood sugar and inject insulin. The project has already entered clinical testing, and its success could free patients from making constant insulin-dosing decisions, and provide a safe, accurate and cost-effective way to help patients maintain healthy blood sugar levels.

UCSF has always been at the forefront of diabetes research. Its basic and clinical researchers have led developments in treatment and care of both type 1 and type 2 diabetes. After nearly 20 years of planning, a clinical trial involving a therapy called anti-CD3 was recently launched to prevent diabetes in relatives of those with type 1 diabetes who are at risk (those testing positively for antibodies but who still have beta cell function). This year, UCSF also launched the world's first human clinical trial using an individual's own regulatory T cells for the treatment of type 1 diabetes. By increasing the number of these regulatory immune cells in new onset patients, researchers hope to halt beta cell destruction and bypass the potential side effects and toxicities of drug therapy.

The **Johnson & Johnson Diabetes Institute** facilities provide healthcare professionals with education, training and a space for collaboration with the aim of enhancing the understanding

of diabetes and helping to improve patient outcomes.

Each Institute aims to ensure that diabetes specialists are able to receive skills training and education customized to reflect the needs of patients and providers in their region, as well as supporting proven guideline implementation and an efficient use of resources within diabetes care. The Silicon Valley facility is located in Milpitas, California.

Companies are actively researching delivery methods that include:

- Inhaled insulin powder
- Liquid insulin inhaler system
- Insulin spray, to be delivered as a fine mist to the mouth.
- At least two types of oral insulin, using different delivery technologies
- Transdermal patch

Innovations Underway

San Diego-based diabetes drug developer **Amylin Pharmaceuticals** earned U.S. Food and Drug Administration approval this year to sell a next-generation diabetes treatment known as Bydureon. The weekly diabetes injection, a form of its best seller Byetta, is intended to replace standard twice-a-day injections. European regulators issued their approvals for the drug last year. Bydureon is part of a class of drugs called GLP-1 receptor agonists, which mimic the effect of glucagonlike peptide- 1, a hormone that increases insulin production when blood sugar is high.

Medtronic entered the diabetes space as a manufacturer of insulin pumps, and has since expanded its role to offer continuous glucose monitors. Continuous Glucose Monitoring (CGM) consists of a glucose sensor, a transmitter, and a small external monitor (may be built-in to an insulin pump or a stand-alone device) to view your glucose levels. CGM can be used by type 1, type 2, and gestational diabetes patients who would like better glucose control to improve the health and quality of their lives.

Tandem Diabetes Care last year received U.S. regulatory clearance to market the first-ever touchscreen insulin pump, known as the t:slim Insulin Delivery System. The device features a thin design, a vivid color touchscreen and a rechargeable battery. It allows users to upload as much as 90 days of insulin pump or blood glucose meter data using a USB connection.

Additional Resources:

American Diabetes Association
www.diabetes.org/

California: Diabetes Information
Resource Center (DIRC)
www.caldiabetes.org/dirc.cfm

California Diabetes and Pregnancy
Program (CDAPP) - Sweet Success
[www.cdph.ca.gov/programs/
cdapp/Pages/default.aspx](http://www.cdph.ca.gov/programs/cdapp/Pages/default.aspx)

California Diabetes Program
www.caldiabetes.org/index.cfm

Centers for Disease
Control and Prevention
www.cdc.gov/diabetes/

Juvenile Diabetes
Research Foundation
www.jdrf.org

National Institutes of Health
Health.nih.gov/topic/diabetes

U.S. Department of Health
and Human Services,
Office of Minority Health
www.omhrc.gov

DID YOU KNOW?

After adjusting for population age and sex differences, average medical expenditures among people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes.

Source: California Department of Public Health

Managing Diabetes



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Diabetes is serious. It is the leading cause of blindness, kidney failure, and amputations and is a significant contributor to heart attacks and strokes. The complications of diabetes are worsened by tobacco use. There is no known cure for diabetes, but its complications can be delayed or prevented by good diabetes management or control. Studies show that controlling blood sugar, blood pressure, and cholesterol are key to maintaining good health. People with diabetes can manage their disease by maintaining a healthy weight, being physically active, and taking medicine as prescribed. People with diabetes should talk to their doctor about ways to manage their disease.

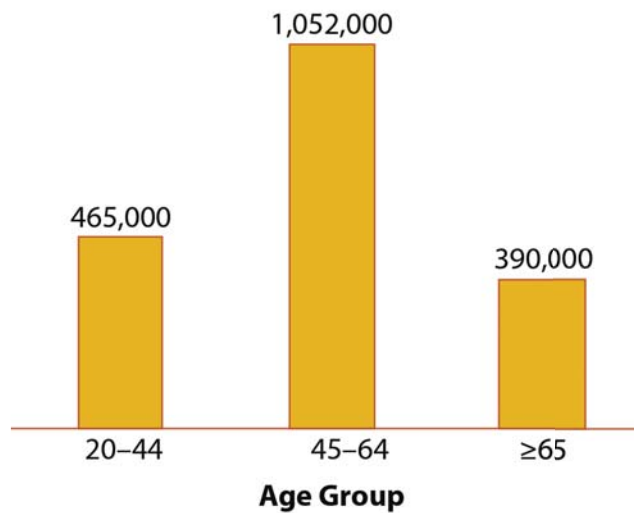
KNOW YOUR DIABETES SYMPTOMS:

- Frequent urination • Extreme hunger • Unexplained weight loss • Sudden vision changes • Sores that are slow to heal • Very dry skin • More infections than usual • Tingling or numbness in hands or feet • Feeling very tired much of the time

If you have one or more of these diabetes symptoms, see your doctor right away.

New Cases of Diagnosed Diabetes

About 1.9 million people aged 20 years or older were newly diagnosed with diabetes in 2010.



Source: Centers for Disease Control and Prevention

CHI-California Healthcare Institute

CHI-California Healthcare Institute is a non-profit public policy research organization for California's biomedical R&D industry. CHI represents more than 275 leading medical device, biotechnology, diagnostics and pharmaceutical companies and public and private academic biomedical research organizations. CHI's mission is to advance responsible public policies that foster medical innovation and promote scientific discovery. CHI's website is www.chi.org. Follow us on Twitter @calhealthcare, Facebook, LinkedIn and YouTube.



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