	<p>Definition, Diagnosis and Pathophysiology</p> <p>Peggy Odegard, PharmD, BCPS, CDE</p>
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	<p>What face does "diabetes" bring to mind?</p> 
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	<p>Significance of DM</p> <ul style="list-style-type: none"><li>◆ 20.8 million people with diabetes in the US<ul style="list-style-type: none"><li>– 7% of the population (up from 5.9% in 1992)</li><li>– 20.9% (10.3 million) 60 years and older!</li></ul></li><li>◆ 14.6 million diagnosed</li><li>◆ 6.2 million undiagnosed</li><li>◆ 41 million people estimated to have "pre-diabetes"</li><li>◆ 2002 costs = 132 billion</li></ul> <p><a href="http://www.diabetes.org/diabetes/statistics">http://www.diabetes.org/diabetes/statistics</a></p>
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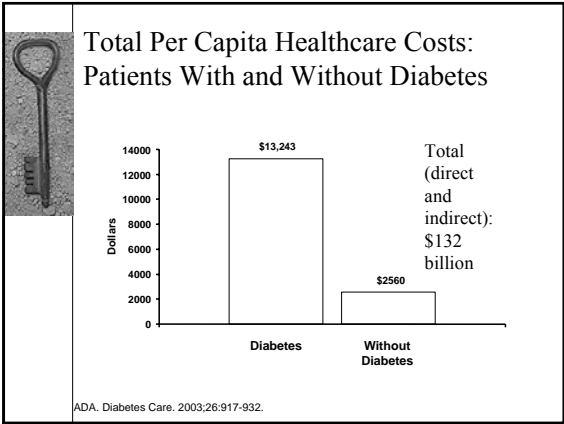
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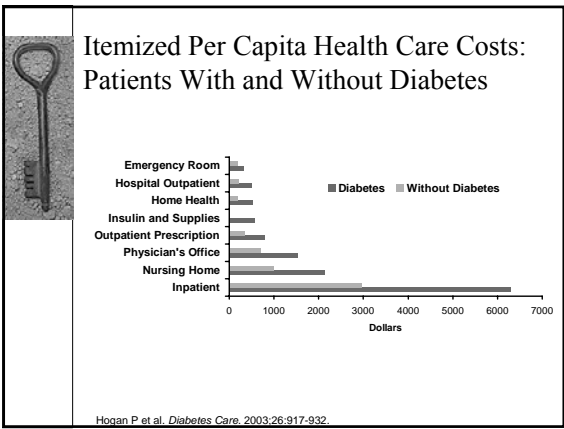
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### What is Diabetes?

- ◆ Diabetes is a chronic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.
- ◆ Insulin is the hormone necessary for normal metabolism of protein, carbohydrates, and fat.

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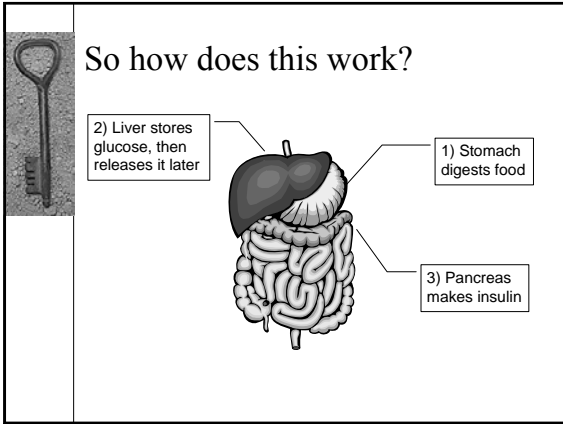
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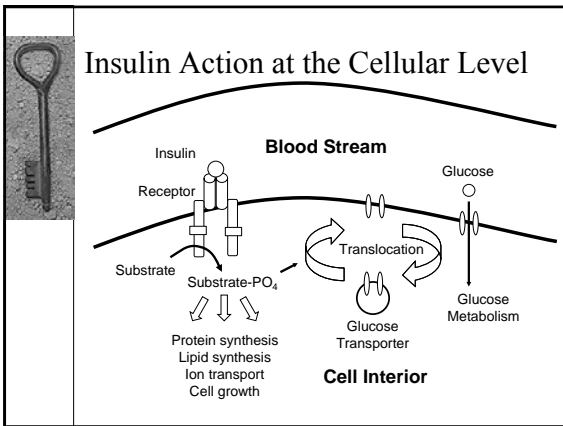
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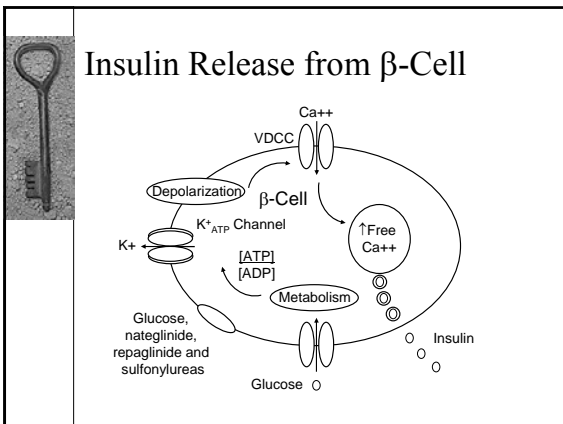
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### Human Insulin Structure

- ◆ Active insulin requires connecting peptide (C-peptide) on proinsulin to be broken off from "A" and "B" chains
- ◆ Free insulin half-life 5.2 +/- 0.7 min
- ◆ Normal daily insulin secretion is 0.5 to 0.7 u/kg/d

The diagram illustrates the structure of human insulin, consisting of two polypeptide chains: the A-chain (21 amino acids) and the B-chain (30 amino acids). The A-chain sequence is Gly1, Ile2, Phe3, Thr4, Ser5, Thr6, Val7, Ile8, Thr9, Asp10, Gly11, Val12, Leu13, Thr14, Ile15, Thr16, Ser17, Thr18, Ala19, Thr20, and Asn21. The B-chain sequence is Phe1, Thr2, Ser3, Arg4, Thr5, Val6, Thr7, Ile8, Thr9, Val10, Gly11, Asp12, Thr13, Ser14, Thr15, Val16, Thr17, Ile18, Thr19, Thr20, Val21, Thr22, Ser23, Thr24, Val25, Thr26, Thr27, Ile28, Thr29, and Asn30. Two inter-chain disulfide bonds connect Cys6 of the A-chain to Cys7 of the B-chain, and Cys7 of the A-chain to Cys6 of the B-chain. An intra-chain disulfide bond connects Cys6 and Cys7 within the A-chain.

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### Insulin Effects

<p><b>Enhances</b></p> <ul style="list-style-type: none"> <li>◆ Fat storage (lipogenesis)</li> <li>◆ Liver and muscle storage of glucose as glycogen (glycogenesis)</li> </ul>	<p><b>Inhibits</b></p> <ul style="list-style-type: none"> <li>◆ Fat mobilization for energy (lipolysis and ketogenesis)</li> <li>◆ Glucose release from the liver and muscle (glycogenolysis)</li> <li>◆ Glucose formation from amino acids (gluconeogenesis)</li> </ul>
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### Formation of Ketones in the Absence of Insulin

The diagram depicts the liver as the central site of metabolic activity. In the absence of insulin, several pathways are shown:
 

- Fat:** FFAs (Free Fatty Acids) are released from adipose tissue into the liver. Glycerol is also released from adipose tissue into the liver.
- Muscle:** Glucose is released from muscle into the liver. Proteins are also released from muscle into the liver.
- Liver:** FFAs and Glycerol enter the liver. Ketones are produced in the liver and released into the bloodstream, leading to Ketoacidosis. Glucose is also released from the liver into the bloodstream, leading to Hyperglycemia.
- Insulin:** Insulin is shown as being absent or ineffective, failing to regulate these processes.

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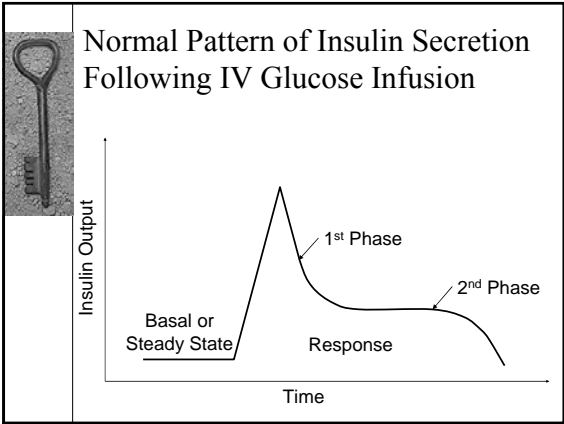
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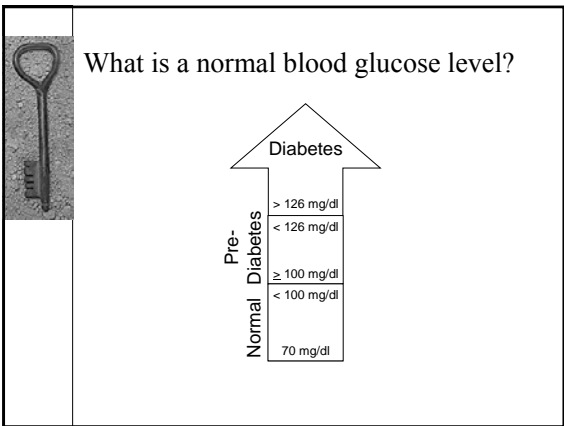
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### Glycemic Control Defined

	FPG	2-h OGTT
Normal	<100 mg/dl	<140 mg/dl
IFG	100-125 mg/dl	NA
IGT	NA	140-199 mg/dl
Diabetes	>126 mg/dl	>200 mg/dl

IFG = Impaired Fasting Glucose; IGT = Impaired Glucose Tolerance  
ADA. *Diabetes Care* 28:S4-S36, 2005; *Diabetes Care* 28:S37-S42, 2005

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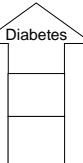
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## Diagnosis of Diabetes

- ◆ Fasting plasma glucose >126 mg/dl on 2 occasions
- ◆ Fasting plasma glucose <126 mg/dl  
Two elevated glucose values during oral glucose tolerance test
  - >200 mg/dl 2 hours after glucose challenge
  - One intervening level >200 mg/dl during 75 g carbohydrate load
- ◆ Nonfasting plasma glucose >200 mg/dl with symptoms (polyuria, polydipsia, unexplained weight loss)




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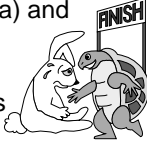
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## What are the symptoms of high blood glucose?

- ◆ Weakness and tiredness (fatigue)
- ◆ Extreme hunger (polyphagia)
- ◆ Frequent urination (polyuria) and thirst (polydipsia)
- ◆ Dry, itchy skin
- ◆ Non-healing skin infections
- ◆ Blurred vision
- ◆ Tingling or numbness in hands or feet




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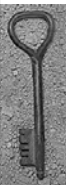
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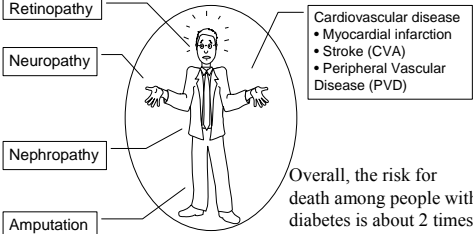
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## So what... why is elevated blood glucose a problem?



Overall, the risk for death among people with diabetes is about 2 times that of people without diabetes

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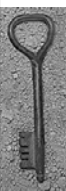
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## Diabetes Complications: Coronary Heart Disease



- ◆ 65% of diabetes deaths are due to heart disease and stroke
- ◆ Compared to patients without diabetes:
  - 2–4 fold increased risk of stroke and CHD
  - In patients with cardiac disease, diabetes increases the death rate by 2–4 times
- ◆ 73% of adults with diabetes have BP >130/80 mm Hg or take drugs for hypertension

CDC National Diabetes Fact Sheet, November 2003.

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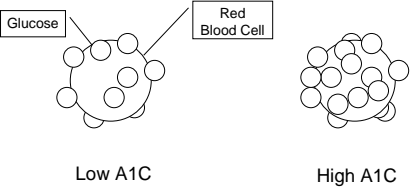
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## A1C Determines Risk of Microvascular Complications



Rohlfing CL et al. Diabetes Care. 2002;25:275; Bonora E et al. Diabetes Care. 2001;24:2023; Bastyr EJ et al. Diabetes Care. 2000;23:1236; Avignon et al. Diabetes Care. 1997;20:1822; De Veciana M et al. N Engl J Med. 1995;333:1237.

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## Diabetes Complications: Blindness



- ◆ #1 cause of new blindness among adults aged 20-74 years
  - 12,000 to 24,000 new cases each year
- ◆ Strongly related to duration of diabetes
  - After 20 years nearly all patients with Type 1 and >60% with Type 2
- ◆ NEI: 90% of lost vision is preventable

CDC National Diabetes Fact Sheet, November 2003.  
National Eye Institute. Facts About Diabetic Retinopathy.  
Available at: [www.nei.nih.gov/health/diabetic/retinopathy.htm](http://www.nei.nih.gov/health/diabetic/retinopathy.htm)

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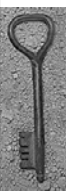
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### Diabetes Complications: Kidney Disease



- ◆ #1 cause of end-stage renal disease (ESRD) – 44% of new cases
  - 42,813 patients were treated for ESRD in 2001
  - 142,963 underwent chronic dialysis or kidney transplantation in 2001
- ◆ \$22.8 billion in public and private funds to treat patients with kidney failure in 2001
- ◆ 26% of Medicare patients with ESRD
- ◆ 40% Type 1 patients eventually develop nephropathy leading to ESRD
- ◆ NIDDK: most ESRD is probably preventable

CDC National Diabetes Fact Sheet, November 2003.

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### Diabetes Complications: Nerve Damage



- ◆ 60%-70% of all patients experience nerve disease
- ◆ Peripheral neuropathy
  - Carpal tunnel syndrome
  - Severe pain, burning or numbness in the hands and feet
  - “Stocking and Glove” distribution
- ◆ Autonomic neuropathy
  - Decreased or slowed GI motility
  - Arrhythmias

CDC National Diabetes Fact Sheet, November 2003.

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### Diabetes Complications: Nerve Damage and Amputations



- ◆ #1 cause of nontraumatic lower extremity amputations
- ◆ 82,000 limbs lost/yr – nearly 225/day in 2001
  - more than 60% due to diabetes
- ◆ 15 – 40 fold increased risk versus population
- ◆ ADA / CDC: >85% of limb loss is preventable
- ◆ Patients with diabetes are more susceptible to many other illnesses and often have worse prognoses.

CDC National Diabetes Fact Sheet, November 2003.

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### Diabetes Complications: Dental Disease



- ◆ Young adults have twice the risk of periodontal (gum) disease as those without diabetes
- ◆ 33% have severe periodontal diseases with loss of gum attachment to the teeth measuring  $\geq 5$  millimeters

CDC National Diabetes Fact Sheet, November 2003.

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### Diabetes Complications: Pregnancy



- ◆ Poor glycemic control before conception and during the first trimester of pregnancy can cause serious complications:
  - 5% to 10% with major birth defects
  - 15% to 20% spontaneous abortions
- ◆ Poor control during the second and third trimesters can result in excessively large babies, posing a risk to the mother and child.

CDC National Diabetes Fact Sheet, November 2003.

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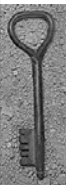
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### ACTIVITY: Do these patients have diabetes?

- ◆ AB – He complains of urinating often (3-4 times each morning before lunch), feels worn out and has a random blood glucose of 214 mg/dl
- ◆ CD – She feels fine but has a fasting glucose of 118 mg/dl

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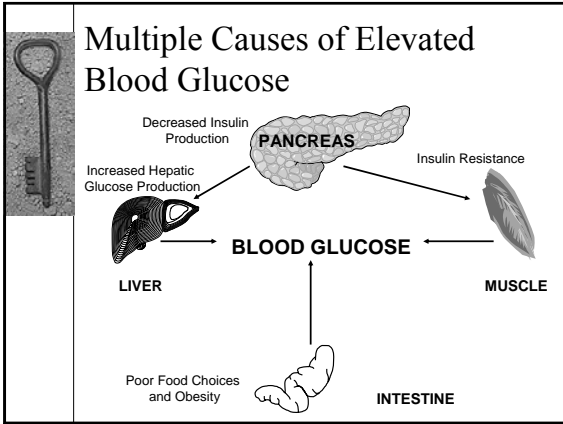
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### Etiologic Classification of Diabetes Mellitus

Classification	Pathophysiology
Type 1	$\beta$ -cell destruction with lack of insulin
Type 2	Insulin resistance with insulin deficiency
Gestational	Insulin resistance with $\beta$ -cell dysfunction
Other specific types	Genetic defects in $\beta$ -cell function, exocrine pancreas diseases, endocrinopathies, drug- or chemical-induced, and other rare forms

Adapted from The Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. *Diabetes Care*. 1997;20:1183-1197. 1-1

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### What are the differences between the two main types of diabetes?

<p><b>Type 1</b></p> <ul style="list-style-type: none"> <li>◆ 10% of people with diabetes</li> <li>◆ May start at any age (usually &lt;30 years of age)</li> <li>◆ Rapid symptom onset</li> <li>◆ Usually thin or lean</li> <li>◆ Inability to produce insulin (caused by destruction of insulin producing cells)</li> </ul>	<p><b>Type 2</b></p> <ul style="list-style-type: none"> <li>◆ 90% of people with diabetes</li> <li>◆ Usually starts after age 30</li> <li>◆ Insidious onset</li> <li>◆ 75% of patients are obese</li> <li>◆ Caused by insulin resistance or a relatively low amount of insulin</li> </ul>
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### Differential Diagnosis of Type 1A Diabetes

Diabetes	Islet Antibodies	Comments
Type 1A	Autoantibody positive >90%	Children: <ul style="list-style-type: none"> <li>◆ 90% non-Hispanic white</li> <li>◆ 50% African American</li> <li>◆ 50% Hispanic American</li> </ul>
Type 1B	Autoantibody negative	Rare in non-Hispanic white
Type 2	Autoantibody negative	If antibody positive, likely latent autoimmune diabetes in adults (LADA) with HLA similar to type1A
Other forms	Autoantibody negative	

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- ### Characteristics of Latent Autoimmune Diabetes in Adults (LADA)
- ◆ Adult age at diagnosis (usually over 25 years of age)
  - ◆ Initial presentation masquerades as non-obese type 2 diabetes (does not present as diabetic ketoacidosis)
  - ◆ Initially can be controlled with meal planning with or without diabetes pills
  - ◆ Insulin dependency gradually occurs, frequently within months
  - ◆ Positive antibodies
    - Islet cell autoantibodies (ICA)
    - Insulin autoantibodies (IAA)
    - Glutamic acid decarboxylase autoantibodies (GAD)
  - ◆ Low C-peptide levels
  - ◆ Unlikely to have a family history of type 2 diabetes.

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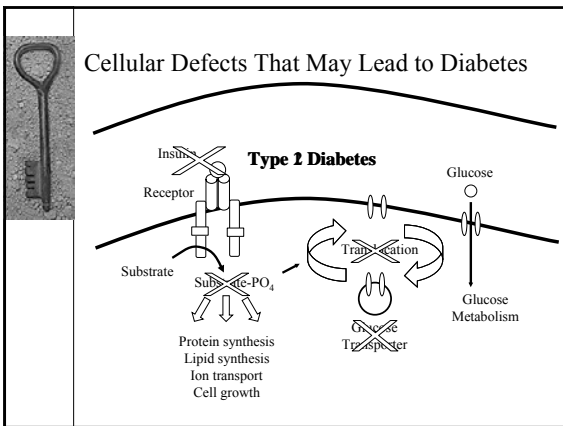
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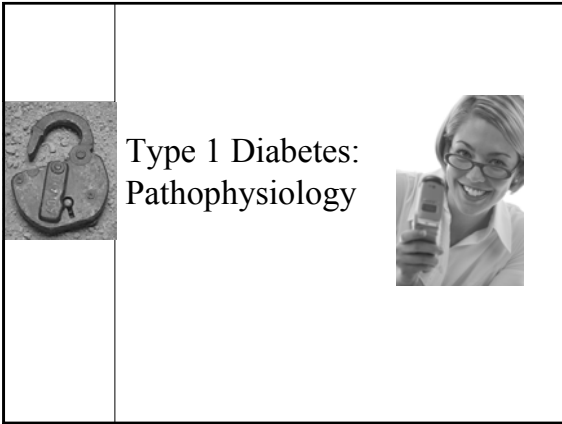
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## Type 1 Diabetes: Pathophysiology

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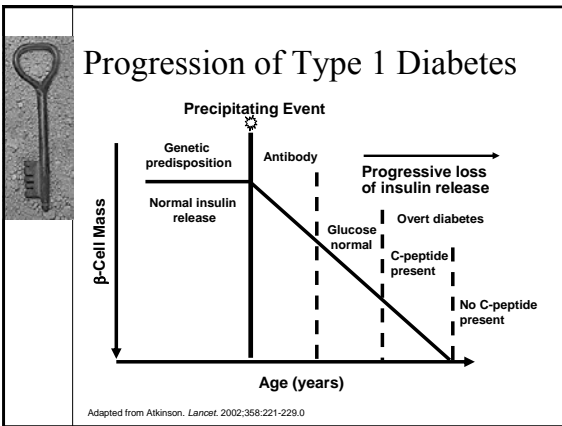
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## Possible Causes of Autoimmune β-cell Destruction

- ◆ Environmental factors
  - Viruses
    - coxsakie
    - rubella
  - Chemical agents
    - nitrosourea compounds
    - bovine milk protein (?)
- ◆ Genetic susceptibility

American Diabetes Association. Clinical Practice Recommendations 2002. *Diabetes Care*. 2002;25(suppl 1):5.

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Genetic Susceptibility to Type 1A Diabetes		
Proband with Diabetes	% Childhood Diabetes (incidence/year)	Islet Autoantibody
General population (US)	0.3% (15 – 25/ 100,000)	3% single Ab 0.3% multiple Ab
Offspring	1%	4.1%
Sibling	3.2%, 6% lifetime	7.4%
Dizygotic twin	6%	10%
Mother	2%	5%
Father	4.6%	6.5%
Father and Mother	10%-25%	
Monozygotic twin	50%	50%

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## Type 2 Diabetes: Pathophysiology



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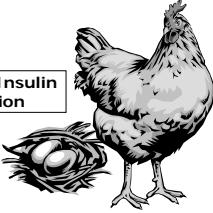
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## What came first?

Impaired Insulin Secretion



Insulin Resistance

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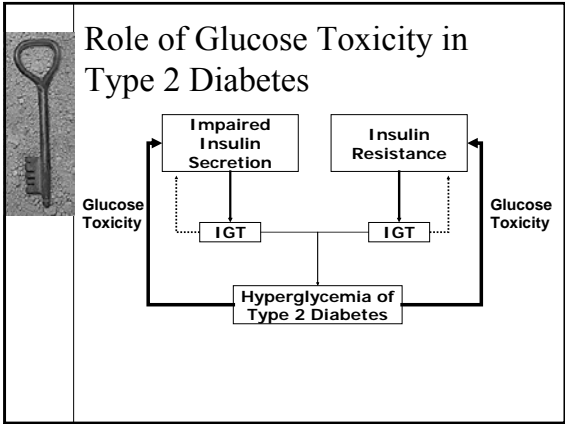
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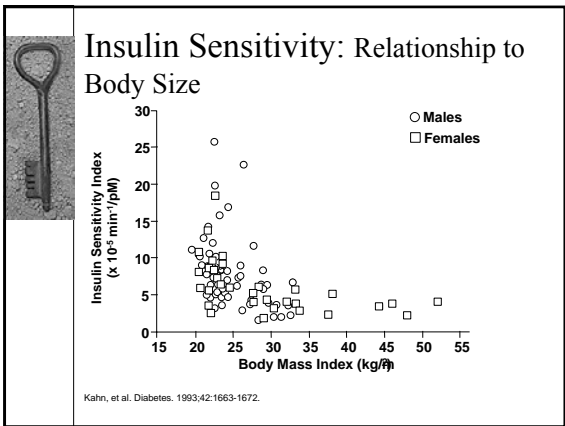
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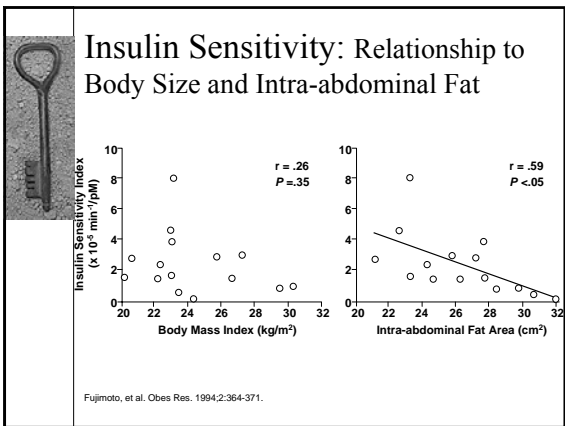
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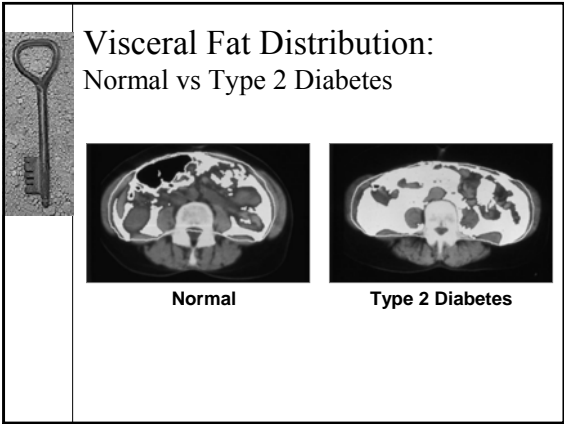
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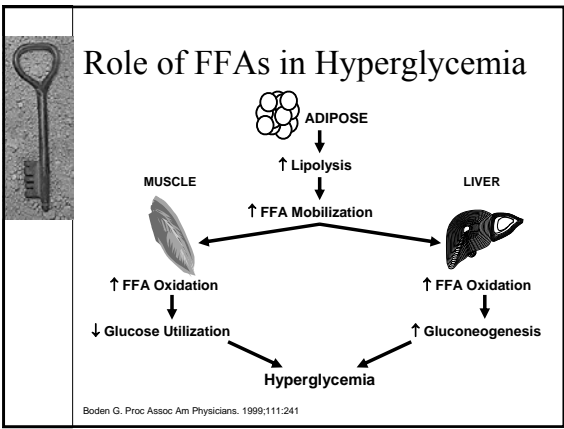
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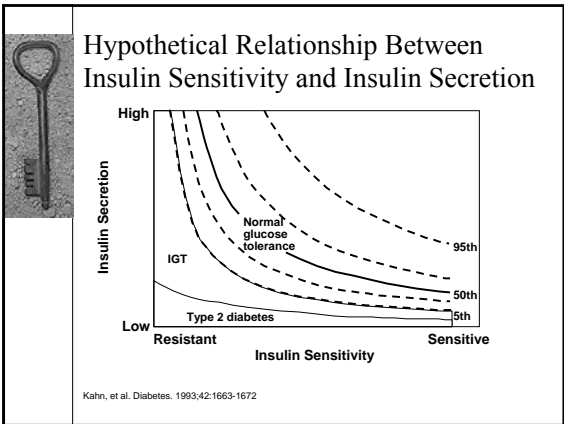
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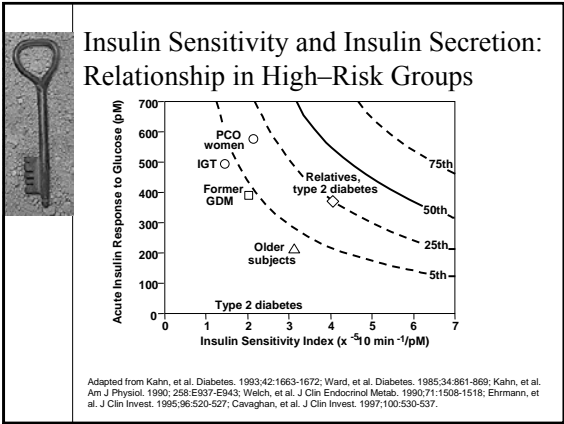
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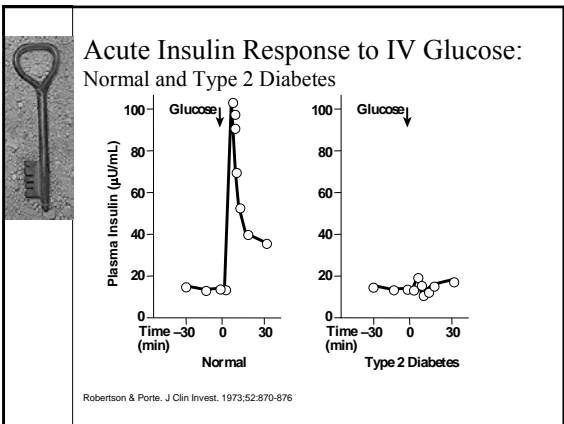
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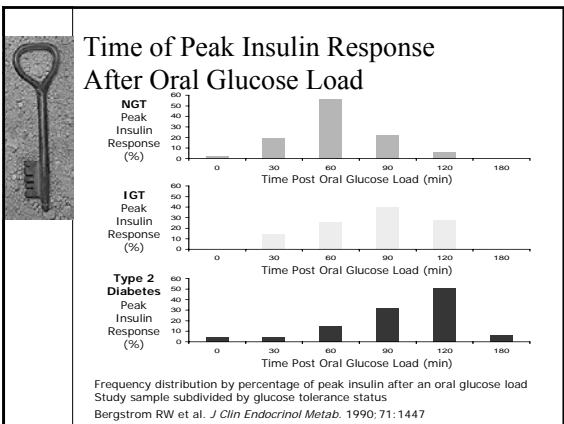
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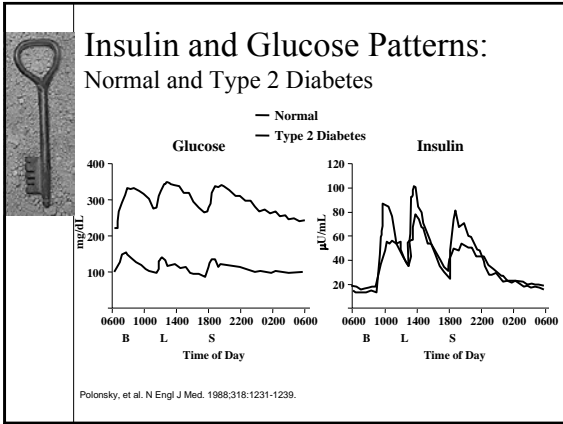
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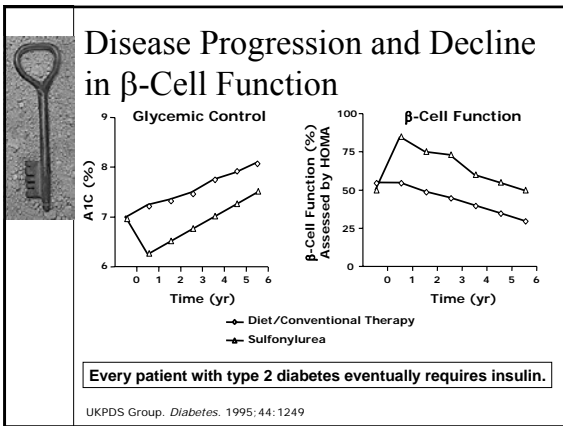
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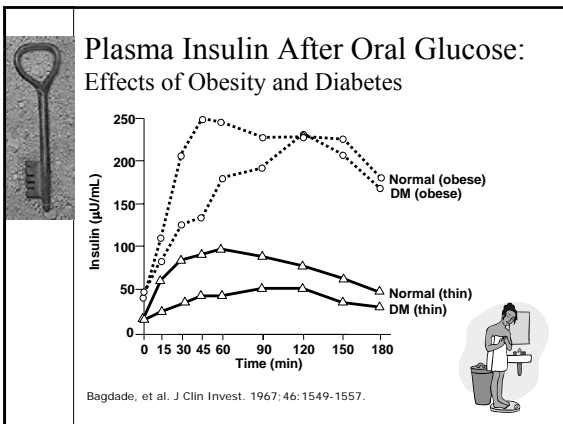
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Drug Induced Hyperglycemia	
Atypical antipsychotics	Increase insulin resistance by altering receptor-binding characteristics
Beta-blockers	Inhibit insulin secretion (especially nonselective agents)
Beta-2 agonists	Increase glycogenolysis and lipolysis
Calcium-channel Blockers	Inhibit insulin secretion due to inhibition of beta-cell cytosolic calcium
Corticosteroids	Cause peripheral insulin resistance and gluconeogenesis
Fluoroquinolones	Inhibit insulin secretion due to blockade of adenosine triphosphate (ATP)-sensitive potassium channels
Niacin	Increases insulin resistance due to increased free fatty acid mobilization
Phenothiazines	Inhibit insulin secretion
Protease inhibitors	Suppress conversion of proinsulin to insulin via calcium-dependent endopeptidases
Thiazide diuretics	1) Inhibit insulin secretion due to hypokalemia 2) Increased insulin resistance due to free fatty acids

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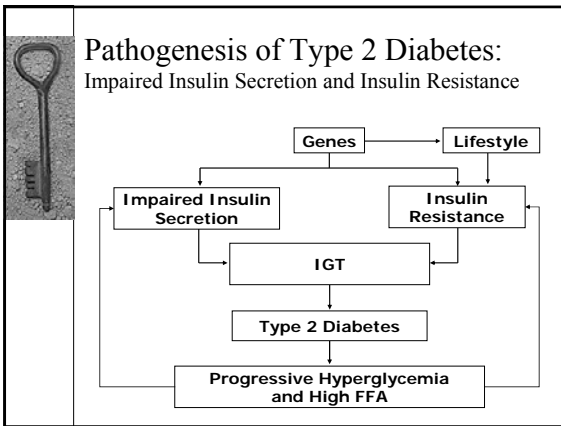
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**ACTIVITY:** What type of diabetes does EF have?

- EF – 22-year-old Non-Hispanic white female is admitted to the hospital through the emergency department after her roommate discovers her lying on the floor of their apartment Sunday morning. EF is still wearing her work clothes from Friday. EF has been boasting that she has been losing weight and that she now wears clothes from high school. Her blood glucose upon arrival to the hospital is 375 mg/dl and she has ketones in her urine.

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**ACTIVITY: What type of diabetes does GH have?**

- ◆ GH – 12-year-old overweight Hispanic male presents with his mother to the pediatrician complaining of frequent bed wetting. His mother reports that he often has to go to the bathroom at school and eats all of the time. At home all he wants to do is sit on the couch and play video games. His blood glucose upon arrival to the office is 215 mg/dl and his weight is up 5 pounds since the last visit 6 months ago.

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**Who should you screen?**

- ◆ There is a difference between screening and testing for diagnosis.
- ◆ Diagnostic tests – performed in patients with symptoms or signs of the disease
- ◆ Screening – identifies asymptomatic individuals likely to have diabetes

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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**General Conditions to Justify Disease Screening**

- ◆ Important health problem with significant population burden
- ◆ Disease natural history is understood
- ◆ Recognizable preclinical (asymptomatic) stage
- ◆ Treatment after early detection yields superior benefits compared to delayed treatment
- ◆ Acceptable reliable tests are available to detect preclinical disease
- ◆ Screening and early treatment costs favorably compare to health expenditures as a whole
- ◆ Screening is a systematic ongoing process

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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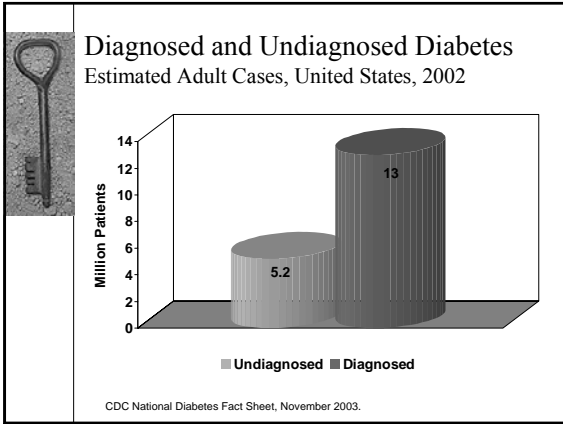
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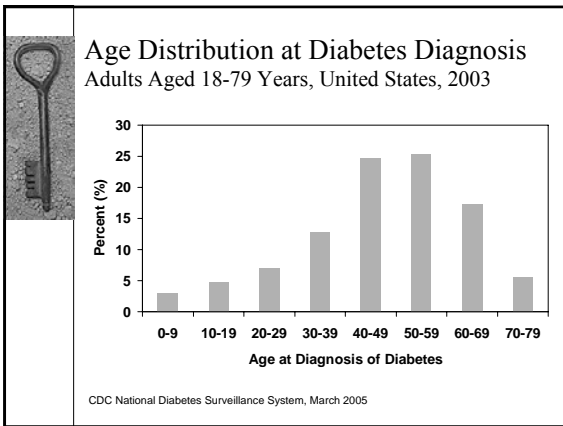
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### Diabetes Prevalence by Race/Ethnicity

Race / Ethnicity	Number of Patients	Percent of Patients in Ethnic Group	Relative Prevalence to Non-Hispanic Whites of Similar Age
Non-Hispanic Whites	12.5 million	8.4%	
Non-Hispanic Blacks	2.7 million	11.4%	1.6 times more likely
Hispanic/Latino Americans	2.0 million	8.2%	1.5 times more likely*
American Indians	110,814	14.9%	2.2 times as likely
Asian Americans			2 times as likely

\* Mexican Americans are 2 times more likely; residents of Puerto Rico are 1.8 times more likely to develop diabetes than Non-Hispanic Whites.

CDC National Diabetes Fact Sheet, November 2003.

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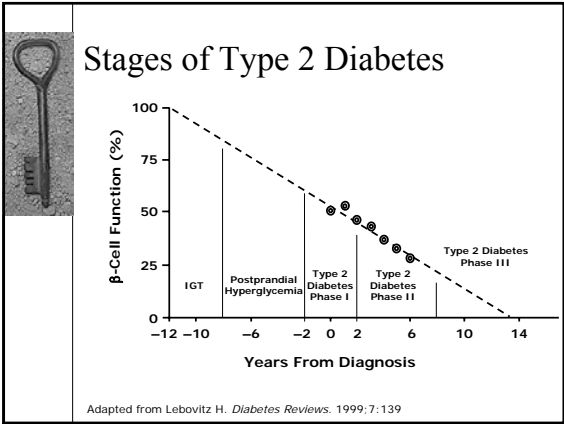
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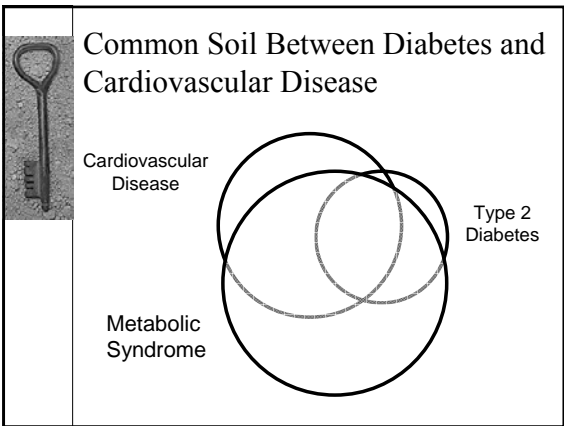
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- ### Metabolic Syndrome Criteria: World Health Organization (WHO)
- ◆ Diabetes or IGT or IFG or insulin resistance together with  $\geq 2$  of the following
1. Central obesity: BMI  $>30$  kg/m<sup>2</sup> and/or Waist to Hip Ratio (WHR)  
Men  $>0.90$   
Women  $>0.85$
  2. BP  $\geq 160/90$  mm Hg
  3. Dyslipidemia  
TG  $\geq 150$  mg/dL and/or HDL-C  
Men  $<35$  mg/dL  
Women  $<39$  mg/dL
  4. Microalbuminuria: AER  $\geq 20$   $\mu$ g/min or Albumin:Creatinine ratio  $\geq 20$  mg/g
- Alberti KGMM, Zimmet PZ, for the WHO Consultation. *Diabet Med*. 1998; 15:539

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## Waist Measurement




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## Metabolic Syndrome Criteria: NCEP-ATP III

- ◆ Diagnosis of metabolic syndrome is made if  $\geq 3$  of following are present

1. Fasting glucose  $\geq 110$  mg/dL
2. Waist circumference
  - Men  $>40$  in
  - Women  $>35$  in
3. TG  $\geq 150$  mg/dL
4. HDL-C
  - Men  $<40$  mg/dL
  - Women  $<50$  mg/dL
5. BP  $\geq 130/85$  mm Hg

Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. *JAMA*. 2001;285:2486

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## Screening: Now, who would you screen?

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**Screening for Autoantibodies Related to Type 1 Diabetes Is Not Recommended**

- ◆ Cut-off values for immune markers (autoantibodies) have not been completely established
- ◆ No consensus as to what action should be taken in the event of a positive result
- ◆ Testing healthy children may only identify a small number (<0.5%)

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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**Criteria to Screen for Diabetes in Asymptomatic Adult Individuals**

1. Consider all individuals  $\geq 45$  years old
  - ◆ particularly in those with BMI  $\geq 25$  kg/m<sup>2</sup>
  - ◆ if normal, repeated at 3-year intervals
2. Consider testing younger individuals who are overweight (BMI  $\geq 25$  kg/m<sup>2</sup>) and have additional risk factors

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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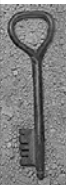
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**Additional Screening Risk Factors for Young Overweight (BMI  $>25$  kg/m<sup>2</sup>) Individuals**

- ◆ High-risk ethnic population (e.g., African American, Latino, Native American, Asian American, Pacific Islander)
- ◆ First-degree relative with diabetes
- ◆ Other clinical conditions associated with insulin resistance (acanthosis nigricans)
- ◆ Polycystic ovary syndrome (PCOS)
- ◆ Habitually physically inactive
- ◆ Hypertensive (140/90 mm Hg)
- ◆ HDL-C  $< 35$  mg/dl and/or TG  $> 250$  mg/dl
- ◆ History of vascular disease
- ◆ History of IGT or IFG on previous testing
- ◆ History of GDM or delivered a baby weighing 9 lb

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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### Criteria to Screen for Diabetes in Asymptomatic Children

- ◆ Overweight
  - BMI >85th percentile for age and sex
  - weight >85th percentile for height or >120% IBW
- ◆ Plus any two of the following:
  - FH of type 2 diabetes in 1st- or 2nd-degree relative
  - Race/ethnicity at high risk
  - Signs or conditions associated with insulin resistance (acanthosis nigricans, dyslipidemia, or PCOS)
- ◆ Testing Specifics
  - Age of initiation: age 10 years or at onset of puberty
  - Test: FPG preferred
  - Frequency: every 2 years

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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### Screening for Type 2 Diabetes in Community Setting Not Recommended

- ◆ Poorly targeted populations
  - Fail to reach high-risk groups
  - Inappropriately test low risk “worried well” or already diagnosed
- ◆ Screening failure due to:
  - Patients with positive screen less likely to seek and obtain follow-up
  - Patients with negative screen less likely to repeat test at appropriate interval
  - Results not discussed with primary care provider
  - Low compliance with treatment recommendations

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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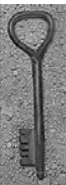
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### Gestational Diabetes Mellitus (GDM)

- ◆ Hyperglycemia first recognized during pregnancy
- ◆ Complicates 4%–5% of all pregnancies
- ◆ Prevalence 1%–14% of pregnancies or about 135,000 cases annually
- ◆ Hormonally induced
- ◆ Usually occurs in women who have insulin resistance and a relative impairment of insulin secretion
- ◆ May remit after delivery; however, 40%–80% eventually progress to type 2 diabetes

ADA. Clinical Practice Recommendations 2002. Diabetes Care. January 2002;25(suppl1) 5.

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### Screening for Gestational Diabetes in Low-Risk Women

- ◆ Low-risk group – Pregnant women who fulfill all of these criteria need not be screened for GDM
  - <25 years of age
  - a normal body weight
  - no family history (i.e., first-degree relative) of diabetes
  - no history of abnormal glucose metabolism
  - no history of poor obstetric outcome
  - not members of an ethnic/racial group with a high prevalence of diabetes (e.g., Hispanic American, Native American, Asian American, African-American, Pacific Islander)

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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### Screening for Gestational Diabetes in High-Risk Women

- ◆ High-risk group – Pregnant women who fulfill any of these criteria should be screened
  - marked obesity
  - personal history of GDM
  - glycosuria
  - strong family history of diabetes
- ◆ Risk assessment for GDM should be undertaken at the first prenatal visit
- ◆ High-risk women without GDM at the initial screening should be re-tested between 24 and 28 weeks of gestation

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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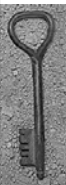
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### OGTT for Gestational Diabetes in High-Risk Women

- ◆ One-step approach
  - Perform a diagnostic 100g glucose OGTT without prior plasma or serum glucose screening
- ◆ Two-step approach
  1. Perform an initial plasma or serum glucose screening 1-h after a 50g oral glucose load
  2. Perform a diagnostic 100g OGTT on women exceeding the initial glucose threshold value

100g OGTT	
Time	Glucose mg/dl
Fasting	95
1-h	180
2-h	155
3-h	140

3-h Results >140 mg/dl are 80% sensitive for GDM; >130 mg/dl are 90% sensitive for GDM

ADA. Diabetes Care 28:S4-S36, 2005; Diabetes Care 28:S37-S42, 2005

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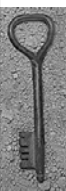
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	<h3>ACTIVITY: Screening Tool</h3> <ul style="list-style-type: none"><li>◆ A physician in your area asks you to develop a diabetes screening tool to increase the number of positive blood glucose tests performed.</li><li>◆ What information would you include?</li><li>◆ What data sources could you use to find the information?</li></ul>
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