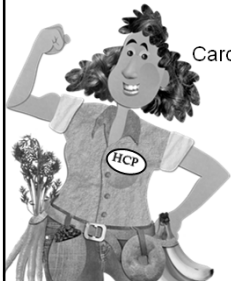


Type 2 Diabetes: How to Use "Farmacy" Over Pharmacy for Prevention and Treatment



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Disclosure to Participants

Conflicts of interest and financial relationships disclosures for Caroline Trapp:

- None
- Nada
- Zip
- Zero
- Not a bit
- Not any
- Not an iota
- Nil
- Zilch
- Naught

Farmacy before Pharmacy



Used with permission Dan Piraro

Objectives

1. Be able to describe limitations of the current treatment paradigm for Type 2 Diabetes.
2. Be able to discuss the scientific research based evidence supporting use of plant-based dietary patterns for Type 2 Diabetes patients and associated conditions.
3. Review specific nutrition considerations of concern for plant-based dietary patterns.
4. Consider useful methods to promote and support behavior change.

A Day in the Life of a Person with Diabetes







Scope of the Problem

- The number of people worldwide with T2DM is expected to DOUBLE by 2030¹
- DM affects @ 26 million people of all ages in the U.S. 1/4 are as yet undiagnosed.
- Cardiovascular morbidity and mortality are 2-4 times those of people without DM.
- DM shortens lifespan by 10-15 years²
- 1/2 - 1/3 of children born in 2000 will develop diabetes unless there are significant changes in diet and activity.²

1. World Health Organization: Country and regional data: prevalence of diabetes worldwide [article online]. Available from <http://www.who.int/mediacentre/factsheets/fs312/en>. Accessed 1/2/2012.

2. Narayan KM. Lifetime risk for diabetes mellitus in the United States. JAMA 2003;290:1884-1890

What Lies Ahead

- Type 2 diabetes (T2DM) was once called “adult-onset” because rare in children.
- 10-fold increase in incidence of T2DM in children over past 2 decades.¹
- Diastolic dysfunction seen in teens with T2DM. Bariatric surgery being used for teens with T2DM.
- The CDC estimates that 79 million American adults aged 20 years or older have prediabetes.²

1. Ludwig DS, Ebbeling CB. Type 2 diabetes mellitus in children: primary care and public health considerations. JAMA. 2001 Sep 26;286(12):1427-30.

2. http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf

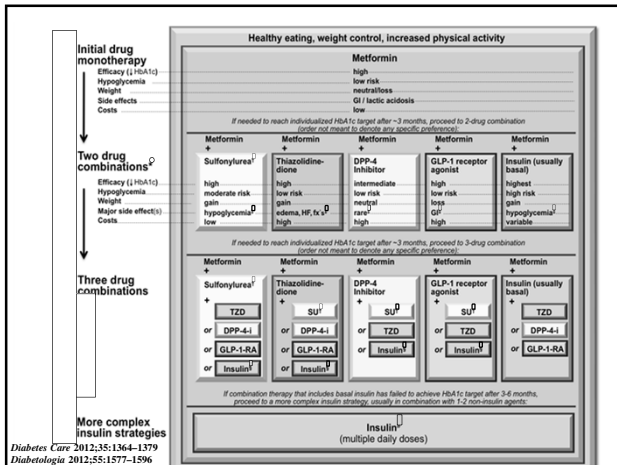
Lessons from 3 Patients - 2006

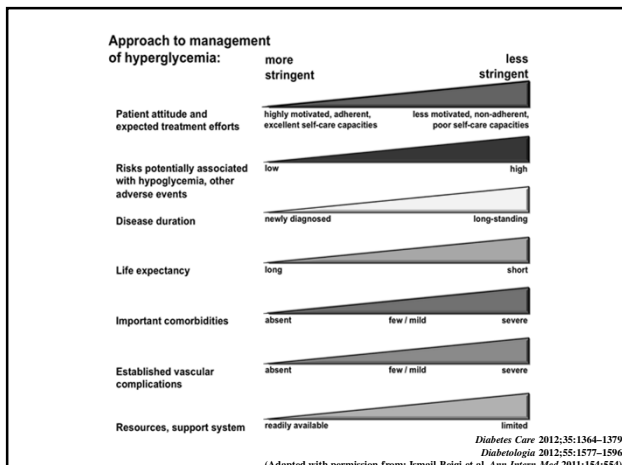
1. 30 lb weight-loss resolved sleep apnea and need to progress to insulin; patient ecstatic to have avoided insulin and surgery
2. A1c above 10% dropped to 6.4% without insulin
3. Depression resolved, able to stop medication

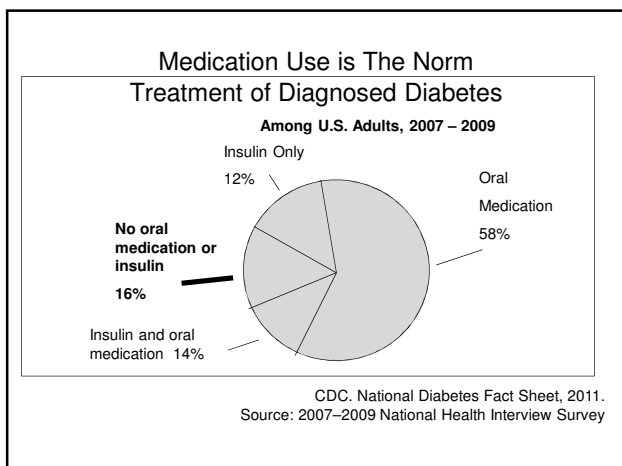
Could simply a change in diet, albeit a significant change, make such a difference?

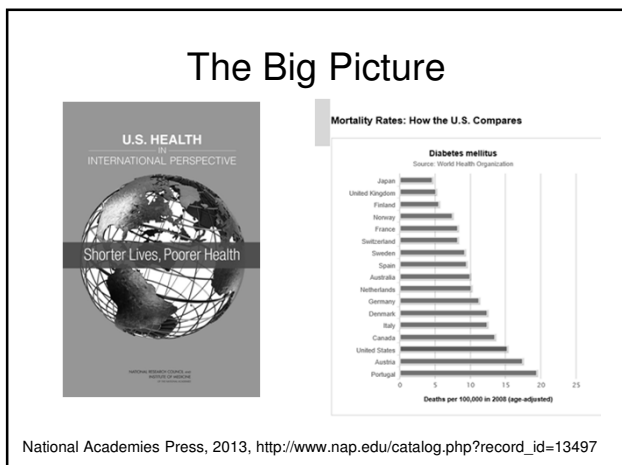
Limitations in Treatment Paradigm for T2DM

- We know lifestyle works, but we are not:
 - Sure how to deliver it.
 - Reimbursed to deliver it.
- We are drug-centric.
- We are under-educated on nutrition.









My office's sample closet and fridge



If all you have is a hammer, everything looks like a nail.



Reviews/Consensus Reports/ADA Statements

Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach

Position Statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)

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 JOHN E. BIRN, MD, MS³
 MICHELLE DANNEY, MD, MS⁴
 ERIK FIMBERG, MD⁵

MICHELLE NADEL, MD⁶
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 RICHARD WOODS, MD⁹
 DAVID R. MATTHEWS, MD, MPH, MS, PhD¹⁰

Glycemic management in type 2 diabetes mellitus has become increasingly complex and, to some extent, controversial, with a widening array of pharmacological agents now available (1–5), mounting concerns about their potential adverse effects and new uncertainties regarding the benefits of intensive glycemic control on macrovascular complications (6–9). Many clinicians are therefore perplexed as to the optimal strategies for their patients. As a consequence, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) convened a joint task force to examine the evidence and develop recommendations for antihyperglycemic therapy in nonsurgical adults with type 2 diabetes. Several guideline documents have been developed by members of these two organizations (10)

and smoking cessation) is likely to have even greater benefits. These recommendations should be considered within the context of the needs, preferences, and values of each patient; individualization of treatment is the cornerstone of success. Our recommendations are less prescriptive than and not as algorithmic as prior guidelines. This follows from the general lack of comparative effectiveness research in this area. Our intent is therefore to encourage an appreciation of the variable and progressive nature of type 2 diabetes, the specific role of each drug, the patient and disease factors that drive clinical decisions (10–13), and the constraints imposed by age and comorbidity (4,14). The implementation of these guidelines will require thoughtful clinicians to integrate current evidence with other constraints and imperatives in the context of patient-specific factors.

PATIENT-CENTERED APPROACH—Patient-centered advice depends on the extension of primary

- Meta-analysis of 13 RCTs (>34,000 patients) that evaluated intensive glucose lowering:
- Limited benefits on all-cause and CV mortality.
- At best, modest benefits for microvascular disease.
- Decreased albuminuria, a trend toward decreased retinopathy, but little else.
- Severe hypoglycemia events doubled.

Adapted from Ann Bullock, MD, IHS
BMJ 2011;343:d4243 doi:10.1136/bmj.d4243

AHRQ Has Identified These Gaps in Knowledge (2011)

- Studies are needed to address the efficacy of treatments for:
 - Patients with type 2 diabetes who have varying levels of underlying cardiovascular and renal disease.
 - Persons of different ethnic groups or variant forms of type 2 diabetes.
- Additional comparative studies are needed including:
 - Comparisons of newer medications.
 - Combinations with basal or premixed insulin and MET or other antidiabetic agents.
 - Additional two-drug combinations.
- Sufficient data on event rates are needed to analyze major clinically important outcomes, adverse events, and long-term complications of type 2 diabetes.

www.effectivehealthcare.ahrq.gov/diabetesmeds.cfm

It is reasonable to reconsider prescribing patterns

- Five major studies published over the past 13 years showed that intensive therapy increases the risk of heart disease, serious side effects and death.¹
- To be approved, diabetes medications must lower blood glucose. The FDA does not require that they prevent complications or extend lives.²

1. <http://drmcDougall.com/misc/2009nl/dec/diabetes.htm>
2. Gandhi GY, Murad MH, Fujiyoshi A, et al. Patient-important outcomes in registered diabetes trials. JAMA 2008; 299:2543-2549.

It is reasonable to reconsider prescribing practices

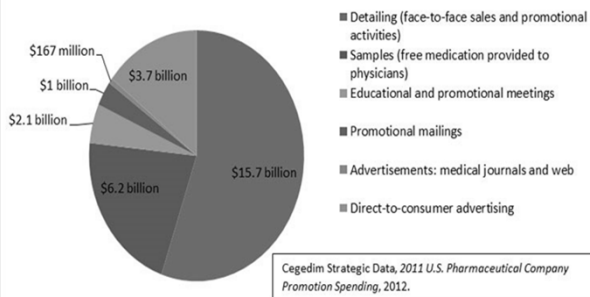
Consider:

- Troglitazone – Off the market 2000
- Insulin inhalation – Off the market 2007
- Exenatide and sitagliptin – concerns re: pancreatitis
- Rosiglitazone – FDA restricted access due to cardiovascular risks May 2011
- Pioglitazone – FDA linked to bladder cancer June 2011



Cartoon by permission of Dan Piraro, creator of Bizarro, Bizarro.com

Expenditure by Type of Pharmaceutical Marketing (2011)





The Pharma Rep vs. the "Farma" Rep



The Broccoli Rep



Ellen Jaffe Jones

Medication Treatment Options

- Metformin
- Sulfonylureas
- Thiazolidinediones
- DPP-4 Inhibitors
- GLP-1 Receptor Agonists
- Meglitinides
- Amylin Mimetics
- Alpha-glucosidase Inhibitors
- Bile Acid Sequestrants
- Dopamine-2 agonists
- SGLT2 Inhibitor
- Insulin

Lactic Acidosis Symptoms

- Trouble breathing
- Vomiting or stomach pain
- Weakness or unusual muscle pain
- Chills or feeling light-headed

Heart Failure Symptoms

- Sudden weight gain
- Fatigue
- Irregular heart beat
- Swelling of belly, ankles or feet
- Loss of appetite or sick to stomach
- Short of breath

Pancreatitis Symptoms

- Persistent severe abdominal pain, sometimes radiating to the back, which may or may not be accompanied by vomiting.

Before taking Victoza, tell your healthcare provider if you have had:

- pancreatitis
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

These medical conditions can make you more likely to get pancreatitis in general. It is not known if having these conditions will lead to a higher chance of getting pancreatitis while taking Victoza.

MedWatch at FDA.gov
Medication Guide Victoza Accessed 6/9/2013

Hypoglycemia

Read this important information before taking:

Levemir (insulin detemir)

[Extra care is needed because Levemir is a high-alert medication.]

High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens with taking them. This means that it is very important for you to know about this medicine and take it exactly as directed.

When taking your medicine

- Know your insulin. Levemir is a long-acting insulin that should be injected below the skin once or twice daily. Other insulins in similar doses, Levemir may be confused an intermediate-acting insulin. When using Levemir, be sure you only shoot the insulin with the evening meal or at bedtime.
- Know how to use it. Use the morning insulin shot the insulin with the evening meal or at bedtime, or 12 hours following the morning dose.
- Prepare your insulin. Mix in about equal parts in other pre-mixed insulin (Levemir, Humalog, Lantus) who also may be mixed in the same syringe with other insulins before injection. Do not separate insulin once mixed.
- Don't reuse or recycle. Check used syringes, needles, pens, and lancets in a sealable hard plastic or metal container. Do not reuse needles, syringes, pens, or lancets. When the container is full, seal the lid and discard the container according to your community guidelines. <http://www.cdc.gov/disease/prevention/diabetes/prevention/insulin.html>
- Don't share. Even if you change the needle, sharing an insulin pen or syringe may spread disease-causing germs and HIV.

To avoid serious side effects

- Avoid mix-ups. If you use more than one type of insulin, make sure each shot, pen, or cartridge looks different. If insulin look similar, put a rubber band around one type to help avoid mix-ups.
- Check your medicine. There are dozens of different insulins on the market, many in similar looking pens, cartridges, or pens. When you pick up your insulin at the pharmacy, be sure it's the right type of insulin.
- Test your blood sugar levels. Carry a quick source of sugar, such as glucose tablets, candy, or juice, to treat low blood sugar. Signs of low blood sugar are listed on the other side of the page.
- Test your blood sugar levels. Ask your doctor how often you should test your blood sugar levels. Keep a log of your blood sugar levels and how much insulin you take each day. Bring the log with you each time you see your doctor.
- Get a periodic lab test. You should have a hemoglobin A1c test at least once a year to determine how well your diabetes is being controlled. The test shows an average of your blood sugar control over a 6 to 12-week period. Your goal is a hemoglobin A1c of 7% or less.

When you should call your doctor

- Call for illness or changes in habits. Your insulin needs may change because of illness, stress, changes in eating habits or physical activity, and other medication you take. Call your doctor if you see persistent these conditions. Never change your insulin doses unless advised by your doctor.

Many types of insulin are available in pen form, which makes the

- High-Alert Diabetes Med Handouts:
- Consumer medsafety.org

Polypharmacy

- 29.4% of elderly patients prescribed 6 or more concurrent drugs.
- 15.7% prescribed one or more potentially inappropriate drugs (produce significant CNS depressant or anti-cholinergic effects).
- 9.3% met both definitions

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2546482/>

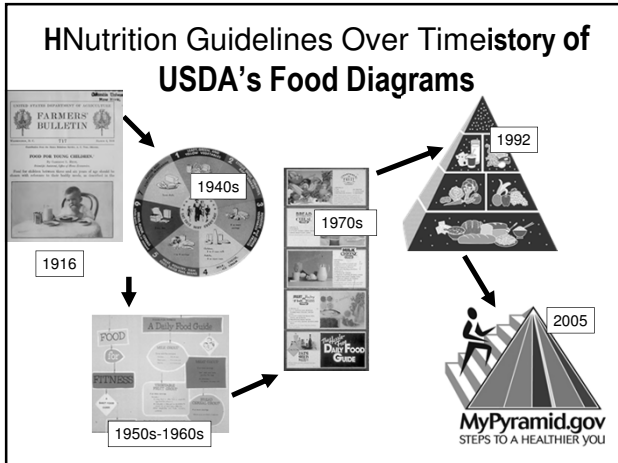
STEPS Mnemonic

1. How **safe** is the drug for various patient populations?
2. Is the drug well **tolerated** or do its adverse effects cause patients to stop taking it?
3. Has the drug been shown to be **effective** for various patient populations?
4. How will the **price** of the drug affect adherence?
5. Will addition of this drug be **simple** or difficult for various patient populations?

Food as Medicine?

“I don’t understand why asking people to eat a well-balanced vegetarian diet is considered drastic, while it’s medically conservative to cut people open or put them on powerful cholesterol-lowering drugs for the rest of their lives.”

Dean Ornish, M.D.



Changes in U.S. Food Consumption Since 1950

Calories	↑25%
Meat (including chicken and fish)	↑68%
Cheese	↑317%
Milk	↓39%
Sugar Sweetened Beverages	↑356%
Butter	↓54%
Added fats/oils	↑67%
Sugar and HFCS	↑39%

- US meat consumption peaked in 2004
- Globally meat consumption is on the rise, and experts predict that meat production will double by 2050.

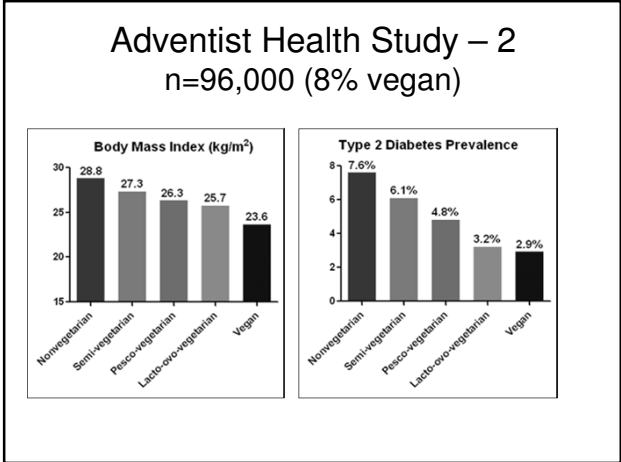
*United States Dept. of Agriculture World Watch Institute
Tile courtesy of Meghan Jardine, RD*

Seventh Day Adventists

- Adventist Mortality Study
 - 25,000 for 21 years (starting in 1960)
 - 40% increased risk for non-veg women
 - 80% increased risk for non-veg men
- Adventist Health Study-1
 - 34,000 for 25 years (starting in 1974)
 - 93% increased risk for non-veg women
 - 97% increased risk for non-veg men

Snowdon DA, et al. Does a vegetarian diet reduce the occurrence of diabetes? *Am J Public Health.* 1985;75:507-512.

Fraser GE. Associations between diet and cancer, ischemic heart disease, and all-cause mortality in non-Hispanic white California Seventh-day Adventists. *Am J Clin Nutr.* 1999;70:5532-5538.



Studies Link Meat to Type 2 Diabetes

- Health Professionals Study (1986-2006), Nurses' Health Study (1986-2006), Nurses' Health Study II (1991-2007):
 - 1/2 extra serving of meat/day increased risk of developing t2dm by 48% in 4 years
- European Prospective Investigation into Cancer and Nutrition (EPIC)-NL Study
 - For every 5% kcal from animal protein there was a concurrent 30% increase in t2dm risk
- NHANES III - High (animal) protein group (20% kcal) had 5 X the incidence of diabetes mortality

Pan A, et al. JAMA Intern Med. 2013;173(14):1328-1335
 Suijs I, et al. Diabetes Care. 2010;33:43-48.
 Levine ME, et al. Cell Metab. 2014; 19:407-417

Meat Consumption Increases Risk of Diabetes

A systematic review compiling data from 12 prior studies found that:

- People who regularly eat meat increase their risk of type 2 diabetes by 21%.
- Regular intake of processed meat increased risk by 41%.

Aune D, Ursin G, Veierod MB. Meat consumption and the risk of type 2 diabetes: a systematic review and meta-analysis of cohort studies. *Diabetologia*. 2009;52:2277-2287.

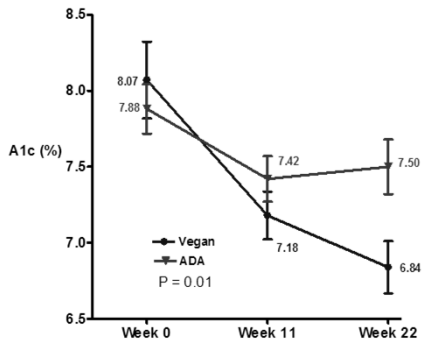
Low-Fat Vegan Diet Intervention

- 22-week RCT with 99 individuals with t2dm
- Compared LF vegan diet (no portion control) to ADA diet
- Both groups significantly improved glucose and CVD risk factors
- Glycemic control: A1C: -0.85% (P=0.01)
- Weight Loss: -3.4 KG (P<0.001)



Barnard N, et al. *Diabetes Care*. 2006;29:1777-1783.

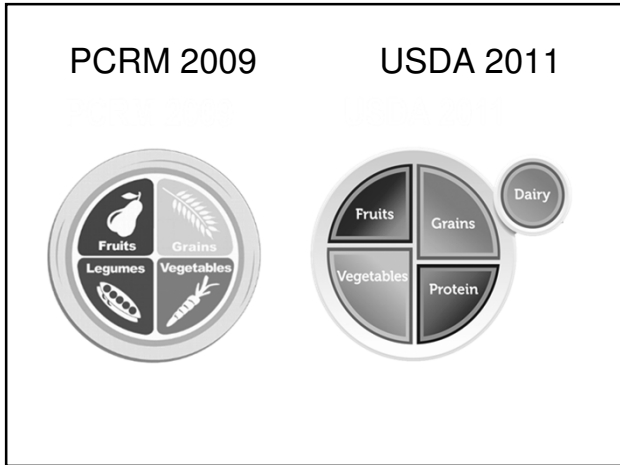
Hemoglobin A1c at Baseline and at 11 and 22 Weeks
Individuals with no medication changes, n = 24 vegan, 33 ADA




Vegan Eating Pattern Intervention for Macro and Micro-vascular Disease

- Dean Ornish, MD: *The Lifestyle Heart Trial*:
 - Regression of atherosclerotic plaque with vegan diet
 - Even more regression occurred after 5 years
 - CMS reimburses for life-style program (Preventive Medicine Research Institute)
- Neuropathy – 21 participants:
 - Vegan diet with 30 min walk
 - Complete relief of pain in 17 of 21 in three weeks

Journal of Family Practice 1995 December; 41(6):560-68 *JAMA*. 1998;280:2001-2007
Crane MG, et al. *Nutr Med*. 1994;4:431-439



Ira



Cholesterol:
 pre-vegan, 242 (June)
 vegan, 180 (October)

Hemoglobin A1c
 pre-vegan, 10.8%
 vegan, 5.1%

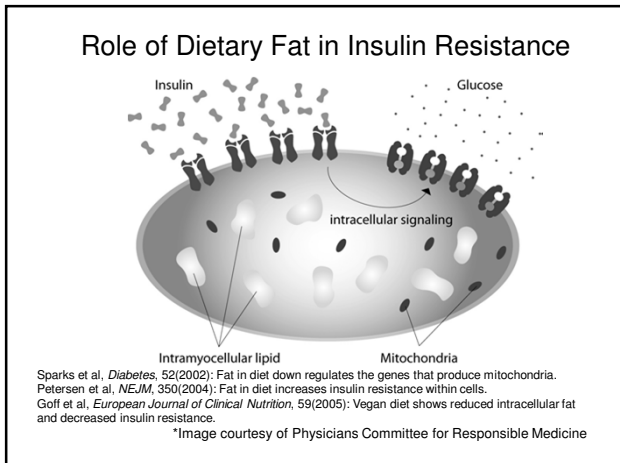
Weight loss: 65 lbs

“You’ve made a believer out of me. Go vegans!”

Michael



Weight loss:
 25 lbs after 2 months
 45 lbs after 4 months
 Maintained for > 1 yr.
 Off 2 diabetes pills,
 blood pressure pill
 and anti-depressant.



Fat Content

(Percentage of Calories from Fat)

Leanest beef	29%
Skinless chicken breast	23%
Sea trout	32%
White tuna	16%
Broccoli	8%
Beans	4%
Rice	1–5%
Sweet potato or yam	1%

- ### Possible Mechanisms
- Heme-iron
 - Nitrates from processed meats
 - Advanced glycation end (AGE) products
 - Higher consumption of calories
 - Altered gut microbiota:
 - Atkins-type diet negatively altered microbiota
 - Increased metabolites associated with increased CVD
- Koning et al. *Diabetes Care*. 2011;34:1150-1156
 Thomas et al. *Br J Nutr* 2014;112(S1):S1-S18.

Power Plate

- Whole grains
- Vegetables
- Legumes (beans)
- Fruits
- Small amounts of nuts and seeds
- Vitamin B12 (or a multivitamin)





Important Nutrition Considerations

- Protein
- Calcium
- Iron
- Omega-3 Fatty Acids
- Vitamin B12
 - 95% of known cases of B12 deficiency occur in individuals who can not absorb it.
 - Who is at risk?
 - Aim for 2.4 mcg/day

Shift Focus from Carbs to Fat/Cholesterol

- 4 food groups: WG, Fruits, Veg, Legumes
- Total Fat: 10% of calories – @ 20 grams or less
- 0 grams cholesterol
- Unlimited unprocessed/minimally-processed carbohydrates*
- Additional benefit from low Glycemic Index carbs
- Fill up on fiber: @40 grams or more
- Protein: WHO 45-55 grams/day

Barnard N, et al. Diabetes Care. 2006;29:1777-1783.

*Carb-counters will still need to count, but not restrict. Insulin-to-carb ratios may change.

Precautions

- Caveat: Some will still need to count carbohydrates (those who cover meals with insulin).
- Watch for hypoglycemia.
- Watch for hypotension.
- Encourage follow-up with health care provider.

Given our knowledge that one medication usually leads to more, and that medications do not fix the underlying insulin resistance and associated metabolic problems, and that intensive treatment of diabetes with multiple medications has significant costs and risks:

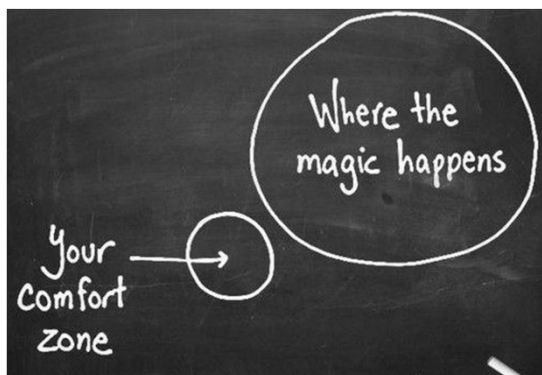
What would our practices look like if medications were reserved as a last resort?

Vital Signs

- Blood Pressure: ____
- Pulse: ____ Weight: ____
- Temperature: ____
- Tobacco Use: Current/Former/Never
- Meat Use: Current/Former/Never
- Dairy Use: Current/Former/Never

Food as Medicine

- What posters would be in the waiting room?
- What patient education materials would we stock?
- How would our discussions go if goal was reversal of diabetes?
- What might our new "prescriptions" look like?
- How could our support staff assist us to answer patient questions, monitor progress, celebrate behavior changes and patients who look and feel good?
- What would we give up? What would we gain?
- What would we need?



Steps to Prescribing PBN

- Try it yourself.
- Gather educational resources.
- Ask if interested in learning more about effective nutrition approach.
- Provide and review resources.
- Discuss meal ideas.
- Discuss precautions: low BG, low BP
- Encourage 100% for 3 weeks.
- Encourage record keeping.
- Schedule f/u.

Adopting a Plant-Based Diet

1 week planning/purging/stocking the kitchen

3 weeks of 100%

Or

Week 1: Vegan breakfasts

Week 2: Vegan breakfasts and lunches

Week 3: Vegan three meals a day

Replace Prescription Pad with Grocery List



Replace This... With This

Hot Dog → Bean and Salsa Burrito

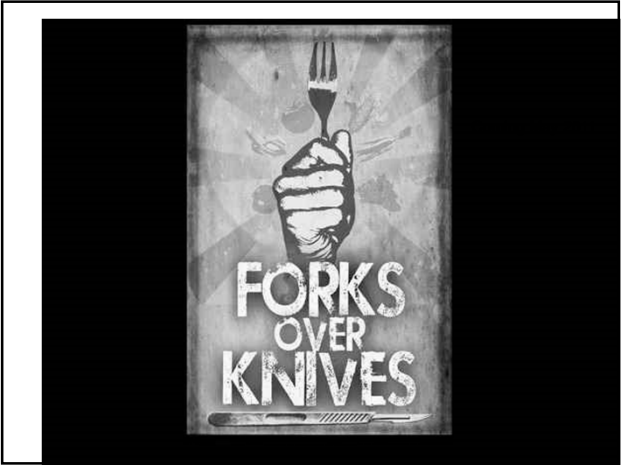
Cheese Pizza → Cheeseless Pizza with Extra Vegetables

Beef burger → Veggie Burger or Grilled Portabella Mushroom

Soda Pop → Water

Oily salad dressing → Fat-free vinaigrette

And don't forget, enjoy vegetables, whole grains, potatoes, yams, beans, lentils and fruit!



Healthy People 2020

EAT for Health Act




	Definition	Examples
Ask	Assess frequency of animal food consumption.	"What would you typically eat for breakfast, lunch and dinner?"
Advise	Give clear, specific and personalized behavior change advice, including harms and benefits.	"I'm concerned about the amount of animal products you have in a typical day. Did you know that animal foods have been linked to diabetes, heart disease, cancer (include conditions of specific interest). . . These foods contain saturated fat and cholesterol, and have no fiber. Many diseases improve or are even cured with a plant-based eating pattern."
Agree	Verbally assess patient's willingness to change. Select appropriate treatment goals based on patient's interest and willingness to change behavior.	"Would you like to know more about this? For example, how some people with diabetes have reversed their diabetes with food? And, did it without going hungry?" "How quickly do you want to see improvement? I have Powerful and Extra-Powerful Diet options."
Assist	Provide brief counseling or self-help/education materials. Aid to acquire skills, confidence and social/environmental supports.	"Here is a list of great cookbooks and DVDs, and meal ideas to get started." "What do you think will happen if you don't make these changes?" "What might get in your way?"
Arrange	Schedule follow-up contacts (phone or in person) to provide assistance/support/fine-tuning/referral.	"Let's meet again in two weeks. Bring your diary of meals and a list of questions."

Failure to Launch?

The "5 R's" are a counseling framework with roots in Motivational Interviewing used for productively discuss planning for or failure to make behavior change.

1. Relevance: How would diet change relate to disease status or risk, family or social situation, health concerns, appearance, financial worries, age, etc.
2. Risks: Identify short term and long term risks of not making change.
3. Rewards: What would the benefits be?
4. Roadblocks: Have patient identify and discuss strategies for overcoming barriers.
5. Repetition: Repeat 1-4 at every visit for patient who has not taken action. Tell those who have relapsed that most make repeated quit attempts before successful.

Adopted from: Fiore MC, Jaén CR, Baker TB, et al. *Treating Tobacco Use and Dependence: 2008 Update*. Clinical Practice Guideline. Rockville, MD: U.S. Department of Health and Human Services. Public Health Service. May 2008.




Extra-Powerful Diet

Avoid:
 All animal products
 Fats: all lard, shortening, butter, margarine and limit oils. Avoid products containing these fats.
 Carbohydrates that raise blood sugar:
 Sugar, honey
 Cold cereals made with sugar or white flour
 White and most wheat breads
 Sweets and breads made with white flour


Enjoy:
 Unlimited vegetables, especially all varieties of dark leafy greens
 Unlimited fresh, frozen, dried or unsweetened canned fruits
 Unlimited beans, peas and lentils
 Unlimited grains: Old-Fashioned oatmeal, muesli cereal, bran cereals, brown or white rice, wild rice, barley, quinoa, millet, amaranth, etc.
 Unlimited pasta (egg-free)
 Non-dairy milks (Soy, Almond, Rice)
 Use molasses or agave nectar instead of sugar or honey
 Choose fat-free tortillas, lavash, rye or 100% whole wheat breads
 Small amounts nuts and seeds
 Use a swipe of oil or small amount of oil spray to grease pans, and sauté onions and peppers in water or vegetable broth

Reimbursement



Counseling

- A discussion with a patient and/or family concerning one or more of the following areas:
 - Diagnostic results, impressions, and/or recommended diagnostic studies
 - Prognosis
 - Risks and benefits of treatment options
 - Instructions for treatment options
 - Risk-factor reduction
 - Patient and family education



Evaluation & Management Codes

- >50% of visit spent providing counseling and education
- Based on total, face to face "time spent"
- MD or Mid-Level Provider
 - 99212 = 10 minutes
 - 99213 = 15 minutes
 - 99214 = 25 minutes
 - 99215 = 40 minutes



Billing Based on Time

- Document start time, end time, and # of minutes spent providing counseling/education
- Document the topic(s) covered
 - "ADA Clinical Targets/PCRM Diet guidelines discussed at length. Pt. goal(s) for behavior change, potential barriers, and ideas to overcome barriers reviewed together. F/U visit with log book: 1 month. Visit time: 1:00 PM – 1:25 p.m. Counseling: 15 minutes."

<http://medicaleconomics.modernmedicine.com/print/373952>
<http://www.aafp.org/fpm/2006/0200/p34.html>

Social norms do change



Rx:Food As Medicine for Type 2 Diabetes

Tastes great!
Affordable!
All side effects are good ones!

Thank you!

Caroline Trapp
ctrapp@pcrm.org

Physicians Committee for Responsible
Medicine
