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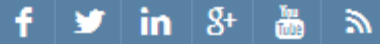
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## Better Healthcare Newsletter from Patrick Malone

# Avoid diabetes' dire harms



Dear Jessica,

You've heard an earful about the dangers of diabetes since you were a kid. Your parents may have tried to grab back that big bag of Halloween candy by telling you that too much sugar causes this health bane.

It doesn't. Diabetes is a disease in which the blood glucose (sugar) runs too high due to imbalances of the hormone insulin. It's a controllable condition. But as the nation grows grayer and more overweight, health experts are worrying more about a big increase in diabetes, with reason.

### IN THIS ISSUE

It's 2017: Don't we know tons about controlling this too-familiar disease?

Managing a chronic condition with less Big Pharma meddling

A disease with disparities

There's good news, too, in treatment of diabetes

### BY THE NUMBERS

**21 million**

Number of Americans with diagnosed diabetes.

**\$245 billion**

Estimated medical costs, plus lost work and wages for Americans with diabetes.

Diabetes clogs blood vessels: major arteries as well as tiny capillaries. That can play havoc with all kinds of body systems, from circulation to the feet (which are at risk for amputation) to blood vessels in the eyes (blindness from retinal disease) to everything in between, from the heart to your sexual organs..

Diabetes has popped up a lot in the news lately not only because Big Pharma and some other special interests are pushing more medications on us for this disease but also because the price of those drugs is skyrocketing. Diabetics have filed lawsuits and said they're frightened they soon may not be able to afford to keep their condition in check.

It's time for some common sense about diabetes.

## It's 2017: Don't we know tons about controlling this too-familiar disease?



Diabetes afflicts most patients in two general ways: People with Type 1—called juvenile diabetes because it most frequently afflicts children and young adults—make insufficient insulin or none because their bodies attack the pancreas where this hormone is made. They need to take insulin daily.

Type 2 diabetes is far more common, tends to affect middle-aged and older patients, and occurs in people whose bodies do not make or use insulin well. They may be treated in various ways, depending on how advanced their diabetes may be.

## No. 7

Diabetes' ranking as cause of death in the U.S. This figure may be under-reported.

## No. 1

Diabetic retinopathy, a common complication of diabetes, is the leading cause of blindness in American adults

## 91%

Price percentage increase for a vial of one type of insulin between 1996 and 2017.

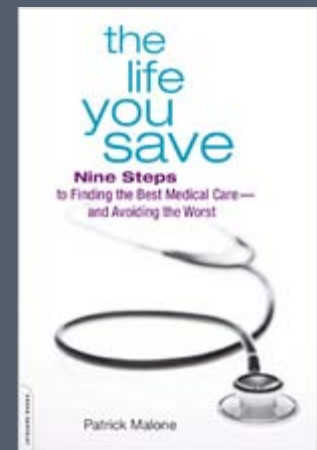
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[The Life You Save](#)

[Nine Steps to Finding the Best Medical Care — and Avoiding the Worst](#)



Diabetes also may develop in some women during pregnancy and go away after they give birth. (This "gestational diabetes" is why an important part of prenatal care is a fasting blood sugar test.) It also may occur in patients with cystic fibrosis. And it can be inherited.

Diabetes has been a [scourge throughout history](#). Over time, physicians and scientists noted the ties between the disease and copious urination as well as sugar in the urine. As they grew to understand how organs function, they determined the pancreas' key role in creating insulin, the hormone that helps glucose from food get into cells for nutrition and energy. Canadian researchers [won the Nobel Prize in 1923](#) for their breakthrough work on the hormone (more about them in just a bit). It took a while but insulin has been refined, and combined with diet and other drugs and therapies, care for diabetes has vastly improved, changing it into a chronic rather than a lethal condition.

The disease, however, too often goes undiagnosed, and those with diabetes don't always strictly adhere to their prescribed health regimens.

Wreaking health havoc

[Unchecked high glucose can damage blood vessels and other body systems, leading to problems such as: heart disease, stroke, kidney disease \(diabetic nephropathy\), eye woes \(diabetic retinopathy, diabetic macula edema, cataracts, and glaucoma\) and blindness, dental disease, nerve damage \(diabetic neuropathy\), sexual dysfunction, and foot problems.](#)

Despite campaigns against it, [diabetes remains the seventh leading cause of death](#) in the United States (where its incidence likely is under-reported because, for example, other factors may be listed ahead of it on death certificates), and it is the leading cause of kidney failure, lower-limb amputations, and adult-onset blindness. Of the [nation's top-cost diseases in 2013](#), diabetes ranked No. 1 with Americans spending \$101 billion on it, compared with \$88 billion each for heart disease and back and

## LEARN MORE



Read our Patient Safety Blog, which has news and practical advice from the frontlines of medicine for how to become a smarter, healthier patient.



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## PAST ISSUES

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A unique and life-giving gift: Participating in medical research  
Has Big Sugar become a public health menace?  
App-solutely not: beware of hype in smart phone health apps

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neck pain, a recent study found. Health experts estimate the total cost for diabetes, including for its care and the lost work and wages of those diagnosed with the disease, [amounted in 2013 to \\$245 billion annually](#), a 41 percent increase over a five-year period.

Although promising research is under way to address genetic factors that may cause Type 1 diabetes, medical scientists, physicians, and public health officials have focused much of their work on attacking the damages that Type 2 diabetes can cause, since 95 percent of those with the disease have this form and its harms can be reduced or averted.

Some experts have taken to calling Type 2's [onset \*diabetes\*](#), noting an "intimate" link between obesity and diabetes. Experts say older Americans can prevent or ease the woes of diabetes, heart disease, and other health conditions by [keeping their weight down, exercising, and eating healthfully](#). It's also smart for myriad reasons, including with diabetes prevention or control, to not smoke. (I've written about how you might want to follow a [common sense, healthful course for the new year](#).)

Doctors also want Type 2 diabetics to hit overall [A-B-C goals to keep the disease's harms in check](#): The A refers to the A1C test their doctors may ask them to undergo. It's a measure of average blood sugar over a three-month period, and it's the gold standard for decision-making about diabetes medications, especially insulin. The B stands for blood pressure, another key measure that diabetics need to check and keep at specified levels. The C stands for cholesterol, the waxy, fatty substance that clogs blood vessels and the heart and can cause problems for diabetics whose circulatory systems may be damaged by their disease.

The fundamental daily issue in Type 2 diabetes' care, however, is the vital step of measuring and keeping blood sugar in control. High-tech devices have made the measurement of blood sugar levels easier and more convenient, though most diabetics still rely on a pin prick, a drop of blood, and test strips. They also

may be prescribed drugs like metformin, which lowers the amount of glucose the liver makes and helps the body use insulin better. They may get other medications that lower blood glucose levels.

### Insulin as a vital treatment

The basic therapy for 6 million or so Type 2 diabetics involves taking insulin, whether by injection (needle, syringe, and pen), pump, inhaler, injection port, or injector spray. There are differing dosages of this critical hormone, and it can be formulated in varying acting speeds, including rapid, short (regular), intermediate, and long. Patients and their doctors may struggle to get the insulin dosage and timing right. If they don't, diabetics—especially if they also manage their diet poorly—can suffer problems like hypoglycemia. It occurs when the blood sugar (glucose) levels fall too low, causing reactions ranging from dizziness and disorientation to loss of consciousness, seizures, and worse.

Highly effective Type 2 diabetes care has been around for decades now, and it has allowed tens of millions of Americans to lead productive, mostly normal lives.

One key step for any diabetic is to regularly see a doctor who takes the disease seriously and knows what he or she is doing. I've seen too many cases of indifferent to incompetent care for diabetics, i.e., malpractice, that has resulted in devastating harms like blindness which are preventable with good treatment. See our website on [medical standards of care for diabetic treatment](#) for more on this important topic.

Studies are under way that may advance treatment—including research on bariatric surgery and how it affects diabetes, studies of oral insulin, and work on an artificial pancreas. But for now, why are so many Americans upset over and afraid about diabetes care? Skeptics should have lots of pointed questions for Big Pharma and special interests.

## Managing a chronic condition with less Big Pharma meddling



Remember those Canadian Nobel Laureates who were honored for their path-breaking work that led to the discovery of the beneficial properties of insulin? They did something else remarkable: They elected to forgo riches and sold their patent for the drug to the University of Toronto for one Canadian dollar each (a total of \$3) in hopes of seeing the disease conquered further.

Alas, the university, then turned to pharmaceutical companies and licensed them to make insulin. A peaceful period held for some time before drug makers began to modify insulin, in some beneficial ways, many not. They changed processes so it no longer was derived from animals but was genetically engineered, resulting in fewer side effects for patients. But some drug makers merely tweaked the medication, or modified it in ways that may not be useful to many (for example, by making its effects longer lasting).

Although there were more of them making the drug, Big Pharma players also started jacking up insulin prices. That defied conventional wisdom that with more manufacturers there would be competition to drive down the medication's cost. Further, critics pointed out, the makers' price hikes occurred in lock step and without discernible cause (such as a spike in materials' costs). Diabetics have been howling for months about insulin costs that for one version, for example, rose over two decades from \$21 to \$255 per vial. Another maker's insulin climbed from \$17 per vial in 1997 to \$138 today.

## Diabetics struggle with soaring insulin costs

Some patients told news organizations that they were skimping on or skipping needed insulin doses, despite the high health risks, because they could not afford the soaring cost of their life-changing medication.

Big Pharma and insurers, at best, have conceded that insulin list prices have risen, steeply. But they also insist that the cost to patients, after discounts and coverages, has not gone up so much or suddenly.

The dispute has led to a patients' pricing lawsuit, and it has become part of the larger controversy over sky-high drug prices—which are a leading driver of the rising cost of medical services in the United States.

The current wrangling over diabetes care demands public scrutiny and skepticism, not only because it highlights dubious drug costs and disparities in health (see sidebar) but also because it may affect even more Americans in the days ahead. That's because Big Pharma and special interests have pushed well-intentioned public health experts and medical scientists, in the name of reigning in detrimental diabetes, to look expansively at this condition, creating a troubling characterization of it.

### The catch-all prediabetes label

I've written how medical scientists and health journalists have raised increasing questions about labeling and treating millions of Americans as "prediabetics." In a recent report published jointly by the Milwaukee Journal Sentinel and MedPage Today, reporters showed how, in 1997, the American Diabetes Association changed the definition of Type 2 diabetes to a lower blood sugar threshold. That move immediately classified 1.9 million Americans as diabetic. Then, in 2003, the patient advocacy group widened its disease net with a new definition of prediabetes that ensnared another 25 million Americans. The frenzy was further fed in 2008, when two endocrinology groups

declared that prediabetes could be treated with drugs, if diet and exercise didn't lower blood sugar levels.

This has created a ballooning consumer market for drugs to lower blood sugar. Big Pharma has jumped into it, introducing 30 new and highly popular drugs between 2004 and 2013. Sales of diabetes drugs hit \$23 billion in 2013. But between 2004 and that year, the reporters found, wrote, "none of the 30 new diabetes drugs that came on the market were proven to improve key outcomes, such as reducing heart attacks or strokes, blindness or other complications of the disease ... Instead, the U.S. Food and Drug Administration approved the drugs based on their ability to lower blood sugar levels, what is termed a surrogate measure. Many of the new drugs have dubious benefit; some can be harmful."

Researchers have found the drugs' side effects to include heart problems, cancer, and overdoses that lead to dangerously low blood sugar. One analysis showed that in about 3,300 patient deaths, diabetes drugs approved since 2004 were the "primary suspect." Another study found that 20,000 hospitalizations occurred because of the drugs' use.

The professional organizations that changed the blood-sugar numbers reap millions of dollars a year from Big Pharma, as do many of the individual doctors who sit on panels that make drug and care recommendations. In one case, according to the Journal and MedPage, 13 of 19 members of a 2013 committee received more than \$2 million in speaking and consulting fees since 2009 from companies that make diabetes drugs.

(A new study has found that 80 percent of patient advocacy groups accept funding from Big Pharma and medical device makers, with these sums making up as much as 40 percent of the budgets of some of the groups. The American Diabetes Association, unlike many other such organizations, has [disclosed that it accepted \\$28 million in industry funding in 2014 or 15 percent so of its operating budget](#). The organization emphasizes



that it now details its donors and how much they give, believing that this transparency improves its credibility when it works on behalf of diabetics and their families.)

Over-medicating people who might have or be predisposed to diabetes is dangerous. And even drugs that might benefit some people are being too widely applied. None of the drugs the FDA approved from the 2008 and 2013 panels to treat diabetes was approved to treat prediabetes. But lots of doctors prescribe them for that purpose in what's known as "off-label" use. It's not illegal for practitioners to prescribe off-label, but it is against the law for drug makers to promote them for that purpose.

Let's ask a common sense question, though: Does it make sense to prod Americans to take better care of themselves and to avoid diabetes by creating the sprawling disease status of pre diabetes? Experts contend that as [many as 80 million-plus Americans](#) may be prediabetic. Is that helpful or just a scare tactic?

With diet, exercise, and weight control—as mentioned before, highly effective ways to avert or reduce diabetes' harms—why must Americans so readily resort to taking drugs instead? The nation's struggling now to ensure the access, affordability, safety, and quality of health care for all its citizens. Still, it's simple reality that with every exposure to every kind of medical care, there is increased risk. There are [2017 standards of care for diabetes](#), and, though these have changed some, much of this thinking is familiar—and caregivers, as fallible humans, will need to strive hard to meet these marks. [Poor treatment, errors, and negligence](#) will occur (as long has been the case), and patients will be harmed. We can help reduce this by providing treatment only to those who truly need it.

I'm hoping that you will eat smart, stay trim, and keep moving so that you don't become diabetic and you stay in great health for a long time!

## A disease with disparities



Diabetes is not only a harmful disease, it is full of disparities. Experts seek to surface and study these to improve care.

Its prevalence and burdens are higher for people of color (blacks, Latinos, Native Americans, and those of Asian descent) than for whites. During their lifetime, half of all Hispanic men and women and non-Hispanic black women are forecast to develop diabetes.

Minorities have higher diabetes-related health complications, and higher mortality from the disease.

Some of this may be due to lifestyle factors affecting those of Asian and Hispanic descent, particularly if they are relatively new to the country. Immigrants have but lose protection from diabetes because they undertake greater physical labor and don't eat high-calorie, high-carbohydrate, and high-sugar diets until they begin to assimilate into American society.

Members of some groups may be suspicious of or disinclined to undergo the rigors of insulin treatment. Widely publicized examples of medical experimentation on African Americans, for example, may make some view medical care warily. Other minorities, like Native Americans, may respond differently to insulin when it is given. Some ethnic groups may believe that alternative therapies from their cultures will help them more. Their

## There's good news, too, in treatment of diabetes



Not all diabetes news is negative:

- Federal health officials say that the number of new cases, after a relentless rise, finally has started to dip: There were 1.4 million new reported cases of diabetes in 2014, down from 1.7 million in 2008. Further, the rate of new cases fell by about a fifth from 2008 to 2014, according to the federal Centers for Disease Control and Prevention, which termed this downturn the first sustained decline since the disease started to explode in this country about 25 years ago. Experts are unsure whether the disease has peaked among Americans or if they have begun to heed warnings about preventing or reducing diabetes' harms. Public health officials have pledged to stay atop diabetes trends because the disease tends to appear in older and heavier people, and Americans are growing grayer and wrestling with obesity as a giant national health concern.
- Uncle Sam says progress continues on an initiative led by the federal Food and Drug Administration to foster the creation of an artificial pancreas. The device would mimic the real organ's functions in monitoring blood glucose

cultures may be more fatalistic about diabetes.

Research shows that diabetes afflicts richer, more developed societies over poor ones, largely perhaps due to the higher incidence of obesity in wealthier nations.

Gender also differentiates how diabetics are afflicted. While diabetes dramatically increases the risk of heart disease, doubling its likelihood and that of stroke, the disease's cardiovascular harms are even greater in women. Diabetic females are twice as likely to suffer a second heart attack and four times as likely to suffer heart failure as are women without the disease.

There also are geographic disparities as to which states have the highest estimated numbers of diabetics and whether those with the disease get recommended eye tests, foot exams, A1C blood sugar tests, and whether they check their blood sugar levels daily or attend classes on the disease's management.

Access to high-quality care can make a big difference. All diabetics should consider getting regular care from a true diabetes specialist like an endocrinologist. The American Diabetes Association publishes regularly updated "standards of care" for diabetes treatment, which knowledgeable doctors adhere to. This includes things like annual eye exams for all diabetics, to make sure microscopic disease isn't affecting the retina, the eye's viewing screen. Patients don't notice these effects until permanent vision has been lost, but there are highly effective treatments that done early enough can

levels and automatically releasing appropriate amounts of insulin at the right times. It would be a big step in safety and convenience for diabetics, and the FDA says that technological improvements are bringing the artificial pancreas closer to reality by the day. The issues aren't simple, especially because diabetes is a disease that afflicts different patients in so many varied ways: this means a device will need to be equipped with cutting-edge artificial intelligence as well as exceedingly reliable components (such as its insulin pump).

- Although too few Americans get the regular eye exams they should, those who do, and especially those with diabetes, may find that medical science is making headway in treating conditions that too often have led to blindness. Eye experts say they are seeing promise in drugs to treat diabetic retinopathy, where changes occur in retinal blood vessels that can cause them to bleed or leak fluid, distorting vision. It is one of the leading causes of adult vision loss and blindness. The therapies also may be useful against diabetic macular edema, another disease complication that can lead to swelling of the retina as blood leaks around it. Early detection and treatment is key, and diabetics should undergo intensive eye exams to protect their sight.
- The drug industry has its many quirks, and they are affecting diabetes

prevent loss of vision. See our website's discussion of [diabetes and blindness](#), with some important links.

therapies. The quest for oral insulin seemed to be moving forward, but Big Pharma has slowed its work on this more convenient, easier treatment—mostly because drug makers aren't sure they can make a lot of money on it, with conventional forms of the hormone so accessible. Research continues on ways to make insulin "smarter," with a hunt for forms of the hormone that would switch on when needed, then switch off.

Medical device makers are seeking improvements in blood tests, as well as insulin pumps, sprays, and injectors.

Medical scientists are studying [why patients who undergo bariatric surgeries often see a remission of their diabetes](#), and this may provide new ways to attack the disease. Meantime, other researchers [are backing away, fast, from work that held high promise](#) for opening new paths to battling diabetes. It involved the finding of a supposed liver hormone that prodded insulin production in mice. But the Harvard scientists haven't been able to reproduce their early study results, which they thought suggested there might be a better way to get the body to produce more insulin on its own.

- To repeat, sugar does not cause diabetes. But diabetics—and the rest of us—can suffer health harms due to diets laden with sugar and foodstuffs (carbohydrates) that the body too readily converts into sugars carried by the blood. After years of trying to get Americans to curb their sugar intake,

there are signs of progress, particularly with taxes that try to curb excess consumption of sodas and other sugary drinks, especially by kids. I've written about sugar's harms and how federal officials have launched a campaign to get us to kick our addiction to it.

## Recent Health Care Blog Posts

Here are some recent posts on our patient safety blog that might interest you:

- Back pain is one of Americans' leading debilitating complaints, prompting us to spend billions of dollars annually for relief and costing more than \$100 billion, especially in lost work and wages. But an [influential physicians' group, joining a growing number of other experts, now recommends that we buck up, exercise, keep moving—and stay away from a reflexive reach for drugs, especially powerful painkillers, to deal with aching backs.](#) The American College of Physicians, with guidelines published in the *Annals of Internal Medicine*, concedes it is breaking with longstanding medical views on treating low back pain. But the group's experts said they conducted a “systematic review of randomized, controlled trials and systematic reviews published through April 2015 on noninvasive pharmacologic and non-pharmacologic treatments for low back pain.”
- Some young users are [experimenting with different ways to vape, modifying their e-cigarettes to increase the smoke and the high](#)—and raising more concerns about the health harms of this hot pastime. Researchers say they found that a quarter of the 1,800 or so of the youthful vapers they studied engaged in a practice dubbed “dripping.” They altered their e-cigarettes to expose the normally sealed heating element, and then they poured flavored vaping liquids directly on it. That created a bigger puff of smoke, which, when inhaled, produced a more intense high from the blast of nicotine and other chemicals vaporized from the flavored liquids.
- Traffic, rock concerts, leaf blowers, and blaring head phones — these are among the many noise sources that have played a part in [40 million American adults suffering from hearing losses not caused by their work conditions, Uncle Sam says.](#) The federal Centers for Disease Control and Prevention, based on a study of more than 3,500 people who underwent tests and questioning, estimates that a quarter of Americans ages 20 to 69 suffer hearing impairment that constitutes “a significant, often unrecognized health

problem.” This diminished capacity, especially if untreated, can lead to “decreased social, psychological, and cognitive functioning,” the CDC says.

- Although marijuana is marching toward legalization across the United States, [expectant moms may wish to think long and hard still about smoking or ingesting a substance](#) that has become as ubiquitous in some households as aspirin or a bottle of chardonnay. The New York Times has delved into this discussion, even as other news outlets recently have provided parental warnings about hype over apps for baby care and tossing some toxic homeopathic teething remedies.
- Three researchers—Dr. Harlan Krumholz of Yale Medical School, Connecticut lawyer Jennifer L. Cox, and Yale student Austin W. Jaspers—[deserve credit for publishing a pointed opinion piece in JAMA Internal Medicine](#) detailing the costs and needless obstacles patients confront when they want copies of their own health records. As Krumholz told Reuters of the study’s message about excessive records fees charged by doctors and hospitals: “Higher costs are a higher barrier for people to get their own information. Without that information it is not possible to correct errors in the record, get informed second opinions, donate your data to research – or share with others what is happening with your care.” That’s spot on, doctor, as I have written recently and in my book, *The Life You Save: Nine Steps to Getting the Best Medical Care, and Avoiding the Worst*.

I’ve also been tracking the Republican attack on the Affordable Care Act, aka Obamacare, with [members of Congress catching flak from constituents](#) at town halls at home, offering a [Trumpcare outline](#) filled with retread proposals, and flip flopping on their talking points from [repeal and replace to repair](#). It’s all a click away.

HERE’S TO A HEALTHY 2017!

Sincerely,

A handwritten signature in black ink that reads "Patrick Malone". The signature is written in a cursive, flowing style.

Patrick Malone

Patrick Malone & Associates

MailChimp