FDA Grants Novo a New Look at Long-Acting Tresiba

INHALED INSULIN: AN ADHERENCE GAME CHANGER?

STATE PROGRAMS UTILIZING PHARMACISTS TO BETTER MANAGE DIABETES

www.DiabetesHealth.com
Because we can't redesign thumbs

We designed Levemir® FlexTouch®

The only prefilled insulin pen with no push-button extension

- Delivers from 1 to 80 units
- Available on more than 96% of managed care plans nationwide

Text to Experience FlexTouch®
Text FLEX to 51212 to learn more about Levemir® FlexTouch®

Levemir® FlexTouch®
insulin detemir (rDNA origin) injection

Get in touch with your Novo Nordisk representative or visit levemirpro.com today

*Intended as a guide. Lower acquisition costs alone do not necessarily reflect a cost advantage in the outcome of the condition treated because there are other variables that affect relative costs. Formulary status is current as of March 2014 and is subject to change.

By texting FLEX to 51212, you consent to receive a one-time text message containing a link to the requested information from Novo Nordisk. Your consent is voluntary and you are not required to consent to receive information or other benefits from Novo Nordisk. Standard text messaging rates will apply.

Needles are sold separately and may require a prescription in some states.


FlexTouch® and Levemir® are registered trademarks of Novo Nordisk A/S.
© 2014 Novo Nordisk Printed in the U.S.A. 1014-00023583-1 October 2014
6 Inhaled Insulin: An Adherence Game Changer?

- Healthcare professionals, who see diabetes patients in a clinical setting, face an ongoing challenge: getting patients to adhere to their medication schedules.

22 Student Corner
- Spotlight on Supplements
- Chromium and Type 2 Diabetes

10 State Programs Utilizing Pharmacists to Better Manage Diabetes
- Coordinated health care is a key element in improving patient outcomes and reducing costs.

26 AADE
- Successful Diabetes Management Should Address Cultural Differences

26 In This Issue

28 NCPA
- Support MAC Transparency and Urge Congress to Pass H.R. 244, the MAC Transparency Act

5 Letter From the Publisher
- A Breath of Fresh Insulin

6 In This Issue

B U S I N E S S  B R I E F
9 FDA Approves Two-in-One Diabetes Treatment for Type 2

18 Metformin May Increase Cancer Risk in Smokers

R E S E A R C H  R E P O RT
14 Rural Regions Pay Doctors More Than Urban Areas

21 FDA Grants Novo a New Look at Its Long-Acting Insulin Tresiba

P A T I E N T  P E R S P E C T I V E
Type 1

20 An Error at the Pharmacy

Type 2

24 Life With Type 2: Good Enough for Government Work

D I A B E T E S  C R O S S W O R D  P U Z Z L E
15 Test your knowledge to see how well you understand diabetes medications.

C A R T O O N S
30 A1 Chuckles
A Breath of Fresh Insulin

It looks though something that people with diabetes have hoped for and dreamed about for years has finally popped out of the development pipeline: inhalable bolus insulin.

Sanofi’s recent introduction of Afrezza, an inhalable bolus insulin for both type 1s and type 2s, could be a game changer when it comes to adherence. Sanofi is not only touting the convenience of inhalation versus injection, it’s also saying that Afrezza may increase the number of people with diabetes who adhere to their medication routines.

Also good to hear, Sanofi says it expects that many people who have been holding off on starting insulin because of their fear of needles will be more than willing to try an inhalable form of it. I cover this promising development on page 6, “Inhaled Insulin: an Adherence Game Changer?”

Other highlights in this issue include:

- the increasing number of states that are asking pharmacists to join the fight against the type 2 diabetes epidemic in more significant, hands-on ways (page 10).

- a report on the FDA’s recent approval of Glyxambi from Eli Lilly, a type 2 treatment that combines Lilly’s SGLT-2 inhibitor empagliflozin (brand name Jardiance) with linagliptin (brand name Tradjenta), a DPP-4 inhibitor (page 9).

- after the FDA rejected its long-acting insulin, Tresiba, in 2013 over concerns about the drug’s effects on the cardiovascular system, Novo Nordisk has come back with research it thinks proves the drug’s safety. We cover that development in “Novo Nordisk asks FDA to take a new Look at Tresiba, Its Revamped Long-acting insulin” (page 14).

- Brenda Neugent reports on a Georgia State University study that links our nation’s expanding waistlines to the arrival of Wal Marts various communities (page 21).

- in our patient perspectives, type 1 correspondent Meagan Esler describes what it’s like when a pharmacy makes a diabetes supply error (page 20), while type 2 columnist Patrick Totty discusses when “good enough” A1c numbers come into play (page 24).

- an interesting study from Kaiser Permanente that says while metformin may decrease the risk of lung cancer in non-smoking type 2s, it may actually increase the risk of lung cancer in type 2s who smoke (page 18).

- the American Association of Diabetes Educators offers five tips on how pharmacists can better connect with different cultures (page 26).

- the National Community Pharmacists Association makes the case for greater transparency in generic drug payments under Medicare Part D (page 28).

Don’t forget our crossword puzzle on page 15. This one will test your knowledge of the names for various diabetes drugs.

—Nadia Al-Samarrie, Publisher and Editor-in-Chief
INHALED INSULIN: AN ADHERENCE GAME CHANGER?
Nadia Al-Samarrie

Healthcare professionals, who see diabetes patients in a clinical setting, face an ongoing challenge: getting patients to adhere to their medication schedules. New healthcare laws that require providers to demonstrate better patient outcomes make adherence even more complicated.

No doubt this new inhalable insulin will have a wider appeal to a greater population that has been on the fence about augmenting insulin injections to achieve better glucose control,” says Schwarz. “I believe that Afrezza insulin will have a positive impact on patient adherence. The most common problem with generating adherence is fear of needles. “Statistically, 33 percent of patients with diabetes on insulin dread their injections,” says Stefan Schwarz, Afrezza US Commercial Lead for pharmaceutical manufacturer Sanofi. “Accepting injection as a form of therapy delays the process. It’s well documented that half of adult diabetes patients who can benefit from insulin therapy defer going on insulin for more than five years. There is a large number of patients who are not in control who should make that step into insulin therapy but are reluctant to do so.”

That’s about to change. Sanofi’s new inhalable insulin, Afrezza, is an option that Schwarz believes will overcome many people’s fear of starting insulin therapy.

“No doubt this new inhalable insulin will have a wider appeal to a greater population that has been on the fence about augmenting insulin injections to achieve better glucose control,” says Schwarz. “I believe that Afrezza insulin will have a positive impact on patient adherence. The injection barrier is now removed and the medication delivery device is simple and easy to use, with no special breathing technique required. The rise in adherence will minimize the overall healthcare cost for treating patients with diabetes.

“We are extremely excited to add such an innovative product that addresses a real un-met need of diabetes patients,” says Schwarz.

CLINICAL TRIAL OUTCOME
The clinical trial evaluated both type 1 and type 2 diabetes patients. After 24 weeks,
both populations showed a statistically significant decrease in their A1C with a non-inferiority margin of 0.4 percent.

**PRESCRIPTION INFORMATION FOR AFREZZA:**

**HOW DOES AFREZZA WORK?**
Unlike the cumbersome size of the Exubera inhalable insulin device from Pfizer, introduced in 2006 and discontinued in 2007, Afrezza is delivered from a small device that fits in the palm of the hand. It is a powdered insulin that comes in 4- and 8-unit dosages and is used as a rapid-acting insulin, inhaled prior to eating a meal. Schwarz says “Peak insulin levels are achieved in 12-15 minutes and designed to baseline within 180 minutes. The rapid insulin goes rapidly out of the body.” The powdered particles are so small that they easily penetrate to deep lung tissue for rapid absorption.

Afrezza can also be used for a post-prandial hypoglycemia.

**THE FDA’S CONTRA INDICATIONS FOR AFREZZA:**
Afrezza has a Boxed Warning advising that acute bronchospasms have been observed in patients with asthma and chronic obstructive pulmonary disease (COPD). Afrezza should not be used in patients with chronic lung disease, such as asthma or COPD because of this risk. The most common adverse reactions associated with Afrezza in clinical trials were hypoglycemia, cough, and throat pain or irritation.

**COST:**
Walgreen’s cash price is $335 for a box of 90 with 60 eight-unit cartridges and 30 four-unit cartridges. Currently some insurance companies do not cover Afrezza. However, Sanofi has a co-pay assistance program so that patients do not have to pay more than $30 (the maximum benefit is $150 off per prescription depending on the patient’s out-of-pocket costs) for a purchase of one box with 90 cartridges.

**PHARMACEUTICAL INFORMATION FOR AFREZZA:**
The following page is an excerpt from a PDF published by sanofi. To access the entire text, go to: http://products.sanofi.us/afrezza/afrezza.pdf.

Unlike the cumbersome size of the Exubera inhaled insulin device, Afrezza is a small device that fits in the palm of a hand. It is a powdered insulin that comes in 4- and 8-unit dosages and is used as a rapid-acting insulin, inhaled prior to eating a meal.
HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all of the information needed to use AFREZZA® safely and effectively. See full prescribing information for AFREZZA.

AFREZZA® (insulin human) Inhalation Powder
Initial U.S. Approval: 2014

WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE

See full prescribing information for complete boxed warning.

- Acute bronchospasm has been observed in patients with asthma and COPD using AFREZZA. (5.1)
- AFREZZA is contraindicated in patients with chronic lung disease such as asthma or COPD. (4)
- Before initiating AFREZZA, perform a detailed medical history, physical examination, and spirometry (FEV₁) to identify potential lung disease in all patients. (2.5, 5.1)

INDICATIONS AND USAGE

- AFREZZA® is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. (1)

Important limitations of use:
- In patients with type 1 diabetes, must use with a long-acting insulin. (1)
- Not recommended for the treatment of diabetic ketoacidosis. (1)
- Not recommended in patients who smoke. (1)

DOSSAGE AND ADMINISTRATION

- Administer using a single inhalation per cartridge. (2.1)
- Administer at the beginning of a meal (2.2)
- Dosing must be individualized (2.2)
- Before initiating, perform a detailed medical history, physical examination, and spirometry (FEV₁) in all patients to identify potential lung disease. (2.5)

DOSE FORMS AND STRENGTHS

AFREZZA is available as single-use cartridges of: (3)
- 4 units
- 8 units

CONTRAINDICATIONS

- During episodes of hypoglycemia (4)
- Chronic lung disease, such as asthma, or chronic obstructive pulmonary disease (4)
- Hypersensitivity to regular human insulin or any of the AFREZZA excipients (4)

FULL PRESCRIBING INFORMATION: CONTENTS INDEX

WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE

1 INDICATIONS AND USAGE

2 DOSAGE AND ADMINISTRATION

2.1 Route of Administration

2.2 Dosage Information

2.3 AFREZZA Administration for Doses Exceeding 8 units

2.4 Dosage Adjustment due to Drug Interactions

2.5 Lung Function Assessment Prior to Administration

2.6 Important Administration Instructions

3 DOSE FORMS AND STRENGTHS

4 CONTRAINDICATIONS

5 WARNINGS AND PRECAUTIONS

5.1 Acute Bronchospasm in Patients with Chronic Lung Disease

5.2 Changes in Insulin Regimen

5.3 Hypoglycemia

5.4 Decline in Pulmonary Function

5.5 Lung Cancer

5.6 Diabetic Ketoacidosis

5.7 Hypersensitivity Reactions

5.8 Hypokalemia

5.9 Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

7 DRUG INTERACTIONS

7.1 Drugs That May Increase the Risk of Hypoglycemia

7.2 Drugs That May Decrease the Blood Glucose Lowering Effect of AFREZZA

7.3 Drugs That May Increase or Decrease the Blood Glucose Lowering Effect of AFREZZA

7.4 Drugs That May Affect Hypoglycemia Signs and Symptoms

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Teratogenic Effects: Pregnancy Category C

8.2 Nursing Mothers

8.3 Pediatric Use

8.4 Geriatric Use

8.5 Hepatic Impairment

8.6 Renal Impairment

10 OVERDOSAGE

11 DESCRIPTION

11.1 AFREZZA Cartridges

11.2 AFREZZA Inhaler

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

12.2 Pharmacodynamics

12.3 Pharmacokinetics

13 NONCLINICAL TOXICOLOGY

14 CLINICAL STUDIES

14.1 Overview of Clinical Studies of AFREZZA for Diabetes Mellitus

Reference ID: 3533688
FDA Approves Two-in-One Diabetes Treatment for Type 2

Brenda Neugent

The U.S. Food and Drug Administration recently approved a two-in-one diabetes treatment that combines two type 2 treatments.

Glyxambi combines empagliflozin, a sodium glucose cotransporter-2 inhibitor that blocks the absorption of excess glucose by the kidneys so it is released through urine, and linagliptin, a DPP-4 inhibitor that increases the production of insulin by the beta cells of the pancreas while reducing the amount of glucose produced by the liver.

Empagliflozin, known as Jardiance, was approved in August. Linagliptin, known as Tradjenta, was developed through a joint venture between Eli Lilly and Boehringer Ingelheim.

“Half of people with type 2 diabetes do not achieve recommended blood sugar control, making new treatment options more important than ever,” said Mike Mason, vice president of Eli Lilly’s U.S. diabetes division, in a press release.

Glyxambi, when combined with metformin (which suppressed the production of glucose by the liver), has been shown to improve blood sugar control for most patients.

Side effects include inflammation of the pancreas, dehydration and yeast infections. It is not recommended for those with severe kidney problems or those who are on dialysis.
STATE PROGRAMS UTILIZING PHARMACISTS TO BETTER MANAGE DIABETES

B. Douglas Hoey, RPh, MBA, National Community Pharmacists Association CEO

Coordinated health care is a key element in improving patient outcomes and reducing costs. This is particularly true when health care providers work as a team so that the expertise of certain providers are better utilized and the lines of communications become more open, ultimately benefitting patients. High on the list of those who can be positively impacted by this health care model are patients with diabetes or prediabetic conditions. Many with diabetes can better manage or even reverse the body’s inability to produce the proper amount of insulin.

Sobering statistics demonstrate the need to go on the offensive against diabetes. For example, 25.9 percent of seniors have the disease, which is the seventh leading cause of death in the United States according to the National Diabetes Statistics Report.

Since the Affordable Care Act (ACA) became law numerous federal grants have been awarded to the states through the Centers for Medicare and Medicaid Services’ (CMS) Accountable Care Organizations (ACOs) and the Healthcare Innovation, along with the Centers for Disease Control and Prevention’s (CDC) Coordinated Chronic Disease Prevention and Health Promotion. These resources allow financially-strapped states to experiment with coordinate care models on a smaller scale. However, the pilot program trend predates the ACA.

Some of the newer state pilot programs have tapped into clinically-trained medication experts — your neighborhood pharmacists — as an underused asset that can help produce measurable improvement for patients.

Some of the newer state pilot programs have tapped into clinically-trained medication experts — your neighborhood pharmacists — as an underused asset that can help produce measurable improvement for patients. These efforts hope to replicate the success patients that participate in the Asheville Project in North Carolina experience. Patients “were provided with intensive education through the Mission-St. Joseph’s Diabetes and Health Education Center. Patients were then teamed with community pharmacists who made sure they were using their medications correctly.”
A remarkable track record has developed in the nearly two decades since the Asheville Project launched. Its participants have demonstrated improved A1C levels, lower total health care costs, fewer sick days, and increased satisfaction with their pharmacist’s services.

Another way for states to expand utilization of pharmacist-provided care and intervention is by having more pharmacists complete the Diabetes Accreditation Standards-Practical Applications (DASPA) program offered through the National Community Pharmacists Association (NCPA) and the American Association of Diabetes Educators (AADE).

The two-part, continuing education DASPA program allows pharmacists to complete preliminary steps required by CMS “to offer a recognized diabetes education program in their communities”. With the proper certification in hand, CMS deems their facility as being recognized for diabetes self-management education/training (DSME/T) services that can be reimbursed under Medicare Part B. For these pharmacists, lifestyle-focused educational services can be added to the medications they dispense, counseling they offer, and monitoring they provide for diabetes.

DASPA is being implemented in the states as they push forward with coordinated care pilot programs. For example, NCPA, the Missouri Pharmacy Association (MPA) the Missouri Pharmacist Care Network (MO-PCN), and American Health Care (AHC) have worked together to establish a pharmacist care network across the “Show-Me State” to target chronic diseases such as diabetes, where DASPA training is incorporated. Participating pharmacists serve as care managers who meet with patients to support their efforts to reach pre-determined health care goals documented through a simple web-based platform. The documentation is the mechanism through which participating pharmacists are compensated. AHC is the plan provider. A previous AHC-pharmacist initiative known as the Hickory Project returned $8.48 for every $1 spent in investment.

Missouri is unveiling another program that supports pharmacists’ participation in coordinated care programs. MPA is utilizing a grant to facilitate a Pharmacist Service Expansion (PSE) Project. The project supports expanded patient access to care through pharmacist completion of two certification
programs, including DASPA. Based on available funding and PSE’s success, the award can renew annually. MPA is seeking interested pharmacists to apply for a “scholarship” grant award. Selected pharmacists will provide support medically underserved areas. After completing a certification program such as DASPA, pharmacists are awarded the scholarship grant, reimbursing them for the certification program cost.

In Utah, pharmacists will gather this spring for a two-day DASPA training session sponsored by NCPA and the Utah Department of Health (UDOH) Healthy Living through Environment, Policy and Improved Clinical Care (EPICC) program, a furtherance of the state’s commitment to expand the role pharmacists can bring to health care.

In Utah, pharmacists will gather this spring for a two-day DASPA training session sponsored by NCPA and the Utah Department of Health (UDOH) Healthy Living through Environment, Policy and Improved Clinical Care (EPICC) program, a furtherance of the state’s commitment to expand the role pharmacists can bring to health care. UDOH also has conducted an environmental scan to assess the functions pharmacists currently play on health care teams, as well as to break down barriers to expanding the pharmacists’ role.

Previous state-based efforts have already reaped some benefit from pharmacists’ training and expertise. SelectHealth, an integrated health system seeking to provide the best health care possible at the lowest costs, patients with hypertension were referred to a pharmacist who every two to four weeks could order lab work and make medication changes until the blood pressure goals were reached. The University of Utah Health Care, an academic health care system, helped patients with diabetes and hypertension by bringing pharmacists care with physician care together through the sharing of electronic medical records and medical appointments. And the Utah Navajo Health Systems targeted patients with diabetes and offered them pharmacist-delivered care in the form of medical counseling, along with enabling patients to take chronic disease self-management classes.

As these coordinated care pilot programs proliferate there will be documented evidence of the most successful endeavors. Eventually the best practices could be implemented nationally. Pharmacists not only have the requisite skills to participate in these programs they also bring a level of accessibility that is unmatched in the health care industry. Therefore, we believe diabetes and other chronic conditions will be best aided when pharmacists are an integral part of the team approach to health care.
Lose Weight Without Starving Yourself

“I have lost 53 pounds and I feel amazing!”
- Deborah T. (North Salem, IN)

Introducing Almased
Germany’s most popular all-natural dietary supplement formula made from non-GMO soy, yogurt and honey in a unique fermentation process.

- No artificial fillers, flavors, added sugars, preservatives or stimulants
- Gluten-free and diabetic friendly
- Resets your metabolism and keeps it active throughout the diet and beyond
- Maintains healthy blood sugar levels and thyroid function
- Helps you burn fat and retain lean muscle mass

The success of the unique Almased formula has been confirmed in over 15 years of clinical research. Almased is more than a diet, it’s a way of life.

Here’s How It Works
Simply add Almased shakes to your daily diet.

For more details on the four phases of the Almased Diet and delicious recipes, download our free Figure Plan from figureplan.com, enter source code: DPB.

Recommend the Almased Diet to your customers today! Call us toll-free at 1-877-256-2733, x.14 to find out how we support you and your customers. You can find Almased in health food stores, at GNC and the Vitamin Shoppe or visit www.almased.com.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. As always, consult your doctor or health care team before beginning any weight loss program or reducing your dosage of current medications.
New research finds that doctors in rural areas such as the American West are paid more than physicians in highly competitive regions such as Boston or San Francisco.

According to the San Francisco-based startup Doximity, a networking site for physicians, high-cost municipalities actually pay less in salary than rural areas of the country. Making that dream job at a prestigious medical center seem much less desirable.

“High-cost areas actually pay less,” said Jeff Tangney, CEO and founder of Doximity. “Medical school teaches the science of medicine, but not the business of medicine.”

According to Doximity research, physicians in rural regions make about $1,500 on average a year more than doctors in urban areas.

“We believe that the higher rural compensation is a result of more of a supply problem. The demand for doctors stays relatively consistent with population, with some exceptions,” said Doximity spokeswoman Lauren Lloyd. “However, in areas with a lower supply of physicians either due to the number of training programs or the desirability of the location, we’re seeing that those areas are paying higher wages to meet their demand.”

Emergency medicine, family medicine, occupational therapy, and psychiatry were the most sought-after specialties and paid more in Texas, Florida and Minnesota. Doctors in Massachusetts, New York, and California, however, reported the lowest salaries in those specialties.

Essentially, the more in need a region is of a physician in a certain specialty, the higher the compensation. If another doctor in the same specialty moves to the region, salary tends to drop slightly.

“Our data does show that as you add more physicians per capita, you see a decrease in compensation. We also see that areas with high physician shortages, correlate with lower wages as well,” Lloyd said. “The areas receiving higher wages do not necessarily have a shortage of physicians, likely because they’re paying higher wages to meet their demand.”

The information is based on a survey of more than 18,000 Doximity physician members over the course of four months.
DIABETES HEALTH WORD PUZZLE

Test your knowledge to see how well you understand diabetes medications.

If you would like to sign up to receive a weekly puzzle, please email puzzle@diabeteshealth.com. In the subject area write “add me to your weekly word puzzle list.”

If you would like us to create a puzzle for you and our players, send your 8 words to puzzle@diabeteshealth.com and we will post your challenge online. In the subject area write “create my special word puzzle.” We can all have fun posting and solving your word puzzles.

---

diabeteshealth.com Word Scramble Puzzle

MYLIAN

The pancreas produces this hormone to empty your stomach slowly to prevent high blood sugars

CRPEHMYTNOAAITNOB

Two types of medication therapies that are combined.

CARSEAOB

A type 2 medication that prevents enzymes from being digested.

EIAMXEOCEHTD

A type 2 medication that stimulates your pancreas to produce more insulin.

ALPYAEINDNHLNE

A class of type 2 medications that stimulate the pancreas to produce more insulin after eating

The solution to this crossword puzzle is on page 16
DIABETES HEALTH WORD PUZZLE SOLUTION

Test your knowledge to see how well you understand diabetes medications.

If you would like to sign up to receive a weekly puzzle, please email puzzle@diabeteshealth.com. In the subject area write "add me to your weekly word puzzle list." If you would like us to create a puzzle for you and our players, send your 8 words to puzzle@diabeteshealth.com and we will post your challenge online. In the subject area write "create my special word puzzle." We can all have fun posting and solving your word puzzles.

diabeteshealth.com Word Scramble Solution

MYLIAN  A M Y L I N
The pancreas produces this hormone to empty your stomach slowly to prevent high blood sugars

CRPEHYMTNOAIIITNOB  C O M B I N A T I O N
Two types of medication therapies that are combined.

CARSEAOB  A C A R B O S E
A type 2 medication that prevents enzymes from being digested.

EIAMXEOCEHTD  A C E T O H E X A M I D E
A type 2 medication that stimulates your pancreas to produce more insulin.

ALPYAEINDNHLNE  D - P H E N Y L A L A N I N E
A class of type 2 medications that stimulate the pancreas to produce more insulin after eating.
STAND, WALK OR PLAY

AIR FEET INSOLES

REVOLUTIONIZES THE DIABETES AND INSOLE WORLD

We at AirFeet® have created a revolutionary product, one that is sure to assist the Diabetes community. Through our research, we’ve received multiple patents covering our advanced insole designs. AirFeet® uses an Active Flow Media Technology; a non-toxic Glycerin type substance that enables the insole to absorb a foot impact yet move quickly to a new area, ready to absorb the force of the next impact. The Active Flow Media also allows for the insoles to be placed in the freezer which then provides a wonderful cool and soothing effect. This is an obvious home run for those who suffer with hot feet from Diabetes induced neuropathy.

Precisely engineered, the placement of the seals in the design allows the Active Flow Media to move under the foot in an exacting criss-cross and lengthwise pattern. People with diabetes now have a life changing footwear insole that induces massive circulation to the feet and toes. You do not even need to be physically active to receive these benefits. Simply sit and rock your feet heel to toe and you can feel the wonderful sensation under your foot. The sensation is so radically different that first time customers have called it “weird.” In fact, we loved that description so much we now tell people it’s “the best WEIRD you’ll ever feel!” This sentiment is a hallmark of true innovation. While many people shy away from change, early adopters are the ones who benefit from great new technology.

Whether you Stand, Walk or Play, AirFeet® Insoles are life changing revolutionary products. The benefits AirFeet® creates for critical circulation to the feet and toes are unsurpassed. Their natural impact absorption helps those with arthritis. The constant movement under the arch has unmatched results with Plantar Fasciitis. The ability to remove the pressure where corns and bunions exist. In fact, AirFeet® covers too many ailments to list here. Due to their amazingly thin design (the thickness of just two quarters) our insoles can be worn in all of your favorite shoes. High heels, work boots, athletic shoes, business and casual shoes, and yes even your flip-flops and sandals! Wow, no more ugly shoes to deal with! AirFeet® Insoles are also coated with the patented MonoFoil anti-microbial protectant. An earth element compound that destroys mold, mildew, fungi and viral bacteria on contact. This additionally helps protect feet and footwear from unwanted germs and odor.

Join the many thousands and try AirFeet® Insoles today.

Use the special Coupon Code PCDIABETES to receive FREE shipping.
The diabetes drug metformin may also lower the risk of lung cancer – but only for those who don’t smoke.

Smokers, on the other hand, saw an increased risk of lung cancer while taking metformin, which helps control blood sugar levels in diabetes by suppressing the production of glucose by the liver.

“Our results suggest that risk might differ by smoking history. With metformin decreasing risk among nonsmokers and increasing risk among current smokers,” said Lori Sakoda, a research scientist at Kaiser Permanente Division of Research in Oakland, California.

The study included 47,351 diabetic patients 40 years of age and older who had included their smoking status in a health survey completed between 1994 and 1996.

During the 15 years of follow-up, 746 of those patients were diagnosed with lung cancer.

Those using metformin had a 31 percent lower risk of developing adenocarcinoma. The most common form of lung cancer in nonsmokers, if they had never smoked, while smokers using metformin had an 82 percent increased risk of developing small-cell carcinoma, a lung cancer commonly diagnosed in smokers.

The study appeared in the journal Cancer Prevention Research.
Yes!
I would like to participate in your complimentary diabetes educational outreach program. Please send me 50 copies of Diabetes Health to distribute to my patients.

Sign up for the FREE Digital Edition

Email: subscribe@diabeteshealth.com Subject line: Pharmacist DEOP

ALL QUESTIONS MUST BE COMPLETED IN ORDER TO QUALIFY.

1. YES! Please start/renew my DIGITAL subscription to Diabetes Health Pharmacist (bimonthly)

   Yes  ❑ No

2. What are your credentials? (Check all that apply.)
   01 ❑ Government Pharmacist
   02 ❑ Licensed Chain Pharmacist
   03 ❑ Licensed Independent Pharmacist
   04 ❑ Licensed Hospital Pharmacist
   05 ❑ Student
   06 ❑ OTHER

3. How many diabetes patients do you see per month? (Check one.)
   05 ❑ None
   01 ❑ 1 - 25
   02 ❑ 26 - 50
   03 ❑ 51 - 100
   04 ❑ More than 100

4. Of the diabetes patients you see each month, how many are newly diagnosed? (Check one.)
   05 ❑ None
   01 ❑ 1 - 25
   02 ❑ 26 - 50
   03 ❑ 51 - 100
   04 ❑ More than 100

For Fastest Service, scan and email to subscribe@diabeteshealth.com

“I get several online magazines, and I like the way yours is set up. Will be looking forward to future issues.”

Thanks,
DW, RPh
An Error at the Pharmacy

Meagan Esler

When you depend on multiple daily injections to live, you become pretty protective when it comes to the supplies that allow you to stay alive. Recently I had a long work day followed by grocery shopping, followed by a visit to the pharmacy. After a tiring twelve-hour day, I got home a little before 10 p.m. when the pharmacy closed. I went to put away my supply of syringes, but what I found bothered me.

The edge of one of the four syringe boxes showed slight wear. It almost looked like someone had pulled the side out to get into the box without going through the lid. I opened the box top and found I was short an entire pack of 10 syringes. I was shocked, how could this be? I know pharmacies are careful when it comes to supply counts. I counted a couple of times to be sure, but I was right, instead of 100 syringes, the box held 90. I checked all three other boxes and found that they were correct.

I quickly called the pharmacy and was put on hold for a while. The pharmacy tech said she needed me to speak to the pharmacist, but he was with another customer. After another wait, she came back and said that they were out of syringes, but would order more and asked if I would pick them up later in the week. I quickly said yes and felt relieved that they were going to replace them.

I know one pack of syringes isn’t a lot when you take 5 to 7 shots a day, but I’ve had months where I needed to refill my prescription prior to the date my insurance would allow and they gave me a hard time. The pharmacist would say something like “Sorry, you are early, your insurance won’t allow you to refill until next week”. And I’d have to tell them that if they didn’t refill me I’d have to reuse syringes because, after all, you can’t drink your insulin. That always drove my point home and they always found a way to get me more syringes until refill day.

I wondered if maybe this kind of error was happening more often than I knew. Perhaps I’d received shortages in the past that had contributed to my running out of syringes early? Of course it was always possible that I’d simply needed extra injections during those months due to stress or illness, etc.

I have a hard time with being told we used up our allotted syringes for a period of time. Do the insurance companies honestly think we enjoy taking extra injections? I don’t understand how they can be stingy with life saving supplies. I see it all the time with diabetes supplies like insulin, test strips, pump supplies, and syringes, and it really bothers me.

I have been going to the same pharmacy for well over 13 years now. I know pharmacies are incredibly busy places. A friend of mine used to work as a pharmacy tech and she often told stories of being overworked with no breaks and even having to come in on her days off. This error certainly could have been a one-time thing, though, I know I’ll be counting my supplies from here on out and I urge others to do so.
FDA Grants Novo a New Look at Its Long-Acting Insulin Tresiba

Diabetes Health Staff

The U.S. Food and Drug Administration has accepted Novo Nordisk’s bid to resubmit its new long-acting insulin, Tresiba, to the agency significantly sooner than had been expected. The action comes at least a year before most people expected Novo to come back to the agency for the go-ahead to market Tresiba in the United States.

In 2013 the agency rejected Novo’s first submission of Tresiba for marketing approval, citing concerns about the drug’s effects on users’ cardiovascular systems. Novo responded by initiating a long-term study of Tresiba’s cardiovascular effects, a process that was expected to last until 2017.

While it collected data, one of Novo’s major concerns was that Tresiba’s delayed entry into the U.S. market could allow rival pharmaceutical manufacturers to enter this country earlier with their own new insulin products.

However, early this year Novo scientists believed they had collected enough positive data to submit an interim report to the FDA, demonstrating Tresiba’s safety with regard to cardiovascular events. If the report results in an earlier-than-expected FDA approval for Tresiba, Novo would be able to arrive at market in 2016—in time to stake out a major share of business as pharma companies introduce their next-generation insulins and insulin/other drug combinations.

The decision to pin hopes on an interim report was a bit of a risk for Novo. The report’s data are not as extensive as those that would be published in a longer-term study. But the FDA’s decision to accept the report indicates that the agency agreed with Novo that there were enough data to work with.

Tresiba is a once-daily basal insulin that has been approved for sale in Europe and parts of the Middle East as a standalone drug. In Europe, Novo also sells a combination of Tresiba and the company’s signature GLP-1 drug, Victoza, in a powerful and profitable drug therapy called Xultophy. If and when Novo markets that drug combination in the United States, it will only be able to do so after Tresiba has been given the U.S. market go-ahead as a standalone drug. (Victoza is already sold in the United States.)

Denmark-based Novo Nordisk is currently the world’s top insulin manufacturer, in the past reaching $3 billion in insulin sales. The global and U.S. market for insulin is starting to heat up as Novo’s rivals Sanofi and Lilly look to introduce new insulins. Sanofi has received FDA approval for Toujeo, a once-daily insulin with which it intends to replace its popular Lantus brand. Lilly has been working on its own new basal insulin.

While Sanofi may arrive first in the United States with a new insulin, it may have its own set of marketing problems in trying to get users to switch to Toujeo from its very popular Lantus brand. While some market watchers speculated that Sanofi would try to create consumer demand for Toujeo by discounting it as it enters the market, Sanofi has announced that it has no intention of doing so.

Denmark-based Novo Nordisk is currently the world’s top insulin manufacturer, in the past reaching $3 billion in insulin sales. The global and U.S. market for insulin is starting to heat up as Novo’s rivals Sanofi and Lilly look to introduce new insulins.
Dear Student Pharmacist,

I invite you to submit articles regarding public health and outreach projects in which you are involved. Although this magazine’s emphasis is diabetes, your articles need not be limited to that issue. You may also submit concerns and opinions that you wish to share with your fellow classmates regarding pharmacy-related issues.

Publishing your articles is meant not only to acknowledge your concerns and contributions to patient care, but also to let other students know what you are doing. We want to inspire and challenge all of you to go beyond the norm and prove to yourselves the positive impact you can have on our patients and in our profession. CAPSLEAD students, let us know what your projects are. I am looking forward to receiving your articles and learning more about the great things you do for our patients and for the pharmacy profession.

—Dr. Aglaia Panos, Pharmacy Student Development Specialist

Dr. Aglaia Panos, our pharmacy student development specialist, continues to follow her passion by working with students to expand their knowledge and experience in public health issues.

Aglaia Panos, PharmD
VP Student Pharmacist Development Specialist
Pharmacy Planning Services, Inc.
President, Marin Pharmacy Association
aglaia@diabeteshealth.com

Randa Rifai, third-year pharmacy student at Touro University

Cinnamon, chromium, and alpha-lipoic acid are dietary supplements that have been studied for diabetes management, but are not commonly found in daily multivitamins. Chromium* and cinnamon have the least supportive evidence of efficacy, while some studies have found alpha-lipoic acid to be promising, at least subjectively, in reducing the discomforts of peripheral neuropathy.

Alpha lipoic acid, or ALA (not to be confused with alpha-linolenic acid, which has the same abbreviation), is a water- and fat-soluble antioxidant produced by the body to assist in energy metabolism. Foods rich in ALA include spinach, broccoli, and brewer’s yeast. ALA may increase insulin sensitivity and enhance glucose uptake in the muscle cells of people with type 2 diabetes.

The antioxidant chemical structure of alpha-lipoic acid may protect nerves from oxidative damage caused by hyperglycemia in people with diabetes. Improved blood flow around peripheral nerves and regeneration have been found in animal studies of ALA. Several small randomized controlled clinical trials have indicated that ALA noticeably reduces pain, numbness, and tingling compared to a placebo in patients with diabetic neuropathy. These studies used doses ranging from 500 to 1800 mg per day—600 mg was found to be optimal. Side effects of nausea, vomiting, and dizziness occurred at doses of 1200 mg per day and above.

The use of ALA as a supplement is not recommended for treatment or prevention of neuropathy, but may be considered by patients who are symptomatic despite use of approved medications. Patients with thiamine (vitamin B1) deficiency or a thyroid disorder, or who are undergoing chemotherapy, should avoid taking ALA.

Randa Rifai
Chromium is a trace mineral that the body normally uses to aid glucose metabolism. It is found in most foods in small quantities, around two micrograms per serving. Adequate dietary intake is 50 to 200 mcg per day. Clinical trials involving diabetic patients have shown conflicting or minimal reduction of A1C, a long-term indicator of glycemic control in diabetes, although chromium may reduce fasting blood glucose. Several of the studies concluded that the variation in responses to this mineral makes it unsuitable for patients with poor glycemic control, but possibly useful in patients with chromium deficiency.

The supplemental dose of chromium is 200 to 600 micrograms per day. Upset stomach may occur. Chromium supplementation may also increase side effects from the following drug classes and should be avoided in combination with them: beta-blockers, corticosteroids, nonsteroidal anti-inflammatories, insulin, and niacin.

Drugs that reduce stomach acid, such as antacids or proton-pump inhibitors, can decrease absorption of chromium. Chromium may cause problems for those with iron deficiency because it competes with iron for absorption and transport within the body. The picolinic acid found in chromium picolinate may adversely affect neurotransmitter metabolism in central nervous system disorders, including Parkinson disease and disorders treated with antidepressants.

Cinnamon is promoted as an herb that can lower blood sugar, possibly by mimicking the effect of insulin. A review of several clinical trials found that cinnamon lowered fasting blood sugar by a small amount, less than nine mg/dL, in patients with type 2 or prediabetes. The optimal adult dose is not yet known, but a half-teaspoon or one 500 mg standardized dose is thought to be safe. Larger doses may be unsafe because Cassia cinnamon contains coumarin, which is toxic to the liver. Cinnamon may alter the efficacy of drugs processed by the liver and may increased bleeding risk in patients using blood thinners.

Consult your physician before beginning any new dietary supplements. Because hypoglycemia may occur when using any of these supplements, monitor blood sugar carefully, especially if taking prescribed blood sugar-lowering drugs.

*This mineral is often added to multivitamins, particularly “weight-loss” formulations such as “Centrum Specialist Energy.” Check labels to avoid overdose.

—Sources:
2. Natural Standard, Bottom Line Monograph. Alpha-lipoic acid (1,2-dithiolane-3-pentanoic acid).
4. Natural Standard, Bottom Line Monograph. Alpha-lipoic acid (1,2-dithiolane-3-pentanoic acid).
I remember realizing a few years after being diagnosed with type 2 that few authorities were urging me or any other older type 2s to drive our A1c’s much below 6.5%. There were several reasons behind that lack of urgency, including research-derived fears that too tight a control of blood sugar levels could lead to cardiovascular problems.

The jury’s still out on that, since there have been conflicting studies about the good or bad of tight control. But the current U.S. recommendations for “good” A1c’s hover at 6.5% for younger people and 7.0% for duffers like me.

Translated into more accessible terms, those numbers are:

- 7.0% A1c = 154 mg/dL
- 6.5% A1c = 140 mg/dL
- 5.9% A1c = 123 mg/dL (this is near the top of the pre-diabetic range)
- 4.5% A1c = 83 mg/dL (this is considered normal)
- 4.1% A1c = 71 mg/dL (readings below this level can be dangerous for type 2s)

Those first two numbers—154 and 140 mg dL— are pretty high compared to the three that follow. It unsettles me a bit to know that a “pretty good” A1c of 7.0% has a blood sugar level 86 percent higher than normal. Wow.

Knowing that this is considered an acceptable number by the diabetes powers that be, I’m reminded of an old saying, “Good enough for government work.” It has a negative connotation, namely that it’s good enough to pass muster in a bureaucracy where you can’t be fired, but wouldn’t make it in the real workaday world.
(My apologies to government workers who may be reading this. As individuals, many government workers are dedicated, wonderful people. But as a whole, most government bureaucracies—think Department of Motor Vehicles—are under no obligation or pressure to produce good work.)

I think the 6.5% and 7.0% recommendations are based on some unavoidable insights: People can rarely stick to the kind of rigorous food and exercise regime that drive down A1c’s. (I know I couldn’t. I got down to 5.6% soon after my diagnosis, but over the years crept back up to 7.0%). But even the people who can stick religiously to good eating and exercise habits have to face the fact that type 2 is progressive. We can go at it hammer and tong, but sooner or later the disease, in a way still unknown to us, wears at our best efforts.

The very slender silver lining here is that as we age, fighting to dramatically lower high blood sugar counts doesn’t really seem to make as big a difference as researchers once thought. It may be that our bodies have learned somewhat to live and cope with higher counts. Or perhaps the slow damage to our organs over the years reaches a point where there’s not a heck of a lot we can do to undo it. Driving our numbers down becomes less necessary.

I’m not advocating fatalism here, a weary acceptance of the things type 2 does to us. I’m just saying that few of us are equipped psychologically to make type 2 the main focus of our efforts and lives. It’s easy to see how we can slip into an attitude of “good enough for government work.”

Maybe that’s sufficient. Licenses still get issued, the mail still gets delivered, and most roads stay pothole-free—perhaps not at the level of service we’d like, but good enough.
Diabetes, an epidemic in the United States, places an even larger burden on ethnic minorities. Type 2 diabetes is two to six times more common among minorities, including Mexican Americans, African Americans, and Native Americans.

The key to helping any patient self-manage diabetes — from eating healthy to being active to reducing risks — is to tailor the approach to his or her individual needs and lifestyle, notes the American Association of Diabetes Educators. “Individualizing care increases the likelihood that any patient will have success in his or her self-care plan. Addressing cultural influences is an important factor in that individualization,” said Joan Bardsley, MBA, RN, CDE, FAADE, president of the AADE. “Familiarity with the patient’s cultural background is a good place to start.”

The goal of diabetes self-management education is to help patients learn how to incorporate healthy behaviors into their lives in order to prevent the complications of diabetes and improve their quality of life. AADE recommends adopting the following strategies to ensure your recommendations are on target:

1. Encourage activity rather than exercise – While not exactly a dirty word, exercise is not highly valued in some cultures, and can be seen as irrelevant. Instead of pushing your patients to exercise, focus on the various enjoyable ways to be active. Music, which is central to many cultures, can help get your patients with diabetes moving. For example, an African-American teenager who has diabetes and is overweight might not want to go to a Pilates class, lift weights, or ride her bike, but she may enjoy dancing with her friends. Suggest doing activities with family or a group.

2. Emphasize health, not weight loss. In some cultures, weight loss can have negative implications. Mexican Americans, for example, consider a full figure representative of good health and weight loss a sign of disease. Instead of telling your patients to lose weight, ask them to list their goals. Explain how being healthy will lower their blood glucose levels, which in turn will help them achieve those goals, whether
it’s keeping up with the grandchildren or avoiding the complications of diabetes they’ve seen in relatives.

3. Include familiar foods – Patients with diabetes are much more likely to follow a healthy diet if it includes familiar foods. For example, soup is a common main meal in Russia, so one study of Russian immigrants with diabetes adapted the plate-planner method (dividing the plate into fourths — one part for meat, one for potato and two for vegetables) by swapping the plate for a bowl of soup containing similar portions of those food items. Other tweaks include adapting favorite foods to make them healthier, such as baking instead of frying chicken or using dried beans, which are lower in sodium than canned beans.

4. Recruit the family – Many cultures are family-focused, and the support of family members can help patients with diabetes manage the condition. Caution family members to be supportive, not judgmental or scolding, such as by providing positive feedback (“You look great, mom!”), agreeing not to buy sodas and unhealthy foods and suggesting activities they can do together, such as after-dinner walks.

5. Partner up – Work with people from local community and church groups who can be very helpful in providing tips and understanding the culture. Health workers such as diabetes educators who work in the community can help patients design a healthy living plan tailored to them that is respectful of their way of life.

Your patients with diabetes will appreciate your recognition of their culture and will be much more likely to follow a good self-care plan if it includes strategies that reflect those influences. If you want to move in this direction but aren’t sure how to start, a diabetes educator can help.

ABOUT AADE
Founded in 1973, the American Association of Diabetes Educators is a multi-disciplinary professional membership organization dedicated to improving diabetes care through education. With more than 14,000 professional members including nurses, dietitians, pharmacists, and others, AADE has a vast network of practitioners involved in the daily treatment of people with diabetes.
Support MAC Transparency and Urge Congress to Pass H.R. 244, the MAC Transparency Act

H.R. 244 is a bipartisan bill introduced by Representatives Doug Collins (R-GA-09) and Dave Loebsack (D-IA-02) that would bring greater transparency in generic drug payments under Medicare Part D, the Federal Employee Health Benefit Program (FEHBP) and the military’s TRICARE program.

Generic prescription drugs account for approximately 80 percent of drugs dispensed, but the reimbursement system for these medications is a mystery to pharmacists and raises serious questions as to whether the federal government is overpaying the drug plan middlemen, pharmacy benefit managers (PBMs). The contracts independent community pharmacies sign with PBMs for access to their pharmacy networks are non-negotiable and do not disclose the terms and conditions regarding payments for most generic drugs.

Even though pharmacists are reimbursed for generics via Maximum Allowable Cost (MAC) lists, these lists are not updated on a regular basis which frequently results in pharmacists being reimbursed below their acquisition cost for various medications particularly in today’s pharmaceutical marketplace which has been plagued with a series of generic price spikes.

SUPPORT H.R. 793 FOR PHARMACY COMPETITION IN MEDICARE PART D

This bipartisan legislation was introduced by Reps. Morgan Griffith (R-VA) and Peter Welch (D-VT) and it would allow independent pharmacies to at least try and participate in preferred pharmacy networks in Part D. Specifically the bill would allow any pharmacy that is located in a health professional shortage area or a medically underserved to participate in the networks if they can meet comparable terms and conditions that other in-network providers have operated under in the past.

Preferred pharmacy networks have been contemplated within the Medicare Part D program since 2006. However, it wasn’t until more recently that plans implemented preferred networks. In 2013, there were...
several large national Part D plans that featured preferred pharmacy networks, and continued to grow in 2014.

In January 2014, the Centers for Medicare & Medicaid Services (CMS) released an expansive proposed rule that spoke to the inadequacies that exist within these networks. In the proposed rule CMS questioned whether or not these networks are actually saving money for the government and proposed to allow any pharmacy willing to accept a contract’s terms and conditions to offer a preferred cost sharing level. Unfortunately, CMS did not finalize these provisions, making legislation even more critical.

SUPPORT H.R. 592/S. 314 TO RECOGNIZE PHARMACISTS AS PROVIDERS UNDER MEDICARE PART B
Millions of Americans lack adequate access to primary health care because of primary care physician shortages in their communities, despite many of these patients having health insurance coverage. With an additional 36 million individuals potentially gaining health coverage under the Patient Protection and Affordable Care Act, according to Congressional Budget Office estimates, the physician shortages will only be exacerbated. The Association of American Medical Colleges has projected that there will be more than 91,000 fewer doctors than needed to meet demand by 2020.

Pharmacists are capable of playing a greater role in the delivery of health care services. Pharmacists who utilize their education, training, and license can provide services that include health and wellness screenings, managing chronic diseases, administering immunizations, medication management, and working in and partnering with hospitals and health systems to advance health and wellness and helping to reduce hospital readmissions.

Do you have questions? Call NCPA’s government affairs department at (703) 683-8200.
“Enough about low glucose levels. Doesn’t anyone know a horror story about ghosts or something?”

© 2015 Diabetes Health

“...OK, I’ve packed the sleeping bags, fishing poles, tent, pots and pans, meter, syringes, glucose strips... Billy, did you pack your stuff? ...ah, Billy...?”

© 2015 Diabetes Health

Ralph soon encountered one of the undocumented safety hazards of Ed’s blood glucose testing.

© 2015 Diabetes Health

“Well, I’ll know how much insulin to use just as soon as I figure out exactly what this stuff is...”

© 2015 Diabetes Health

E-mail cartoons to a friend! Go to www.DiabetesHealth.com/cartoons to view our cartoon library.
Access DiabetesHealth.com content quickly and easily right from your Android, iOS, or Google phone or tablet with our free App.

**Diabetes Health Mobile** gives you access to the top news articles and blogs posted to our website. You can read articles from our main Top News and Blogs about Type 1, Type 2, Medication, High and Low Blood Sugar, Insulin and Pumps, CGM, Research, The Cure, and Recipes.

See something you like? Post it straight to Twitter and share it with your friends, or email it instead - it's easy with just one tap! Download now!