# Increased Diagnoses of Diabetes Seen in Patients in States with Medicaid Expansion

Researchers examining states that expanded Medicaid coverage under the Patient Protection and Affordable Care Act (PPACA) found a 13% increase in the number of Medicare-enrolled patients diagnosed with new diabetes, according to a study in *Diabetes Care*.[1]

Researchers examined the rate of new diabetes diagnoses, defined as an ICD-9 diagnosis code of 250.x (diabetes) or A1C level greater than 6.4% (46 mmol/mol) within the first 6 months of a calendar year and the absence of both in the preceding calendar year. Researchers used the first 6 months of 2013 as a control period and the first 6 months of 2014 as the study period.

Researchers identified 215 398 patients with newly identified diabetes in the control period, and 218 890 in the study period (an increase of 1.6%). Of Medicaid-enrolled patients with newly identified diabetes, 26 237 were identified in the control period and 29 673 were identified in the study period (an increase of 13%).

In examining new diabetes identification for Medicaid-enrolled patients between states with expanded Medicaid versus nonexpanded Medicaid, researchers found that expanded-Medicaid states had a higher rate of newly identified diabetes. In states with expanded Medicaid, 14 625 patients were identified in the control period compared with 18 020 in the study period, an increase of 23%; in states without Medicaid expansion, researchers identified 11 612 patients in the control period and 11 653 in the study period, an increase of 0.4%.

"This study suggests that in the states that expanded Medicaid under the [PPACA], an increased number of Medicaid patients with diabetes are being diagnosed and treated earlier," the study authors wrote. "This could be anticipated to lead to better long-term outcomes."

1. Kaufman HW, Chen Z, Fonseca VA, McPhaul MJ. Surge in newly identified diabetes among Medicaid patients in 2014 within Medicaid expansion states under the Affordable Care Act [published online ahead of print March 22, 2015]. *Diabetes Care*. doi:10.2337/dc14-2334

## Lung Cancer Leading Cause of Cancer Death for Women in Developed World

Lung cancer is now the leading cause of cancer deaths in women in wealthy countries, according to a report published in *CA: A Cancer Journal for Clinicians*.[1]

Data from worldwide cancer cases in 2012 showed that 14.1 million new cancer cases and 8.2 million cancer deaths occurred in 2012. The burden of cancer diagnosis and death has shifted to less developed countries: 57% of cases and 65% of cancer death worldwide occurred in less developed nations.

For women in developed countries, lung cancer has surpassed breast cancer as the leading cause of cancer death; for women in less developed countries, breast cancer remains the leading cause of cancer death. For men in developed or less developed countries, lung cancer remains the leading cause of cancer death.

Other leading causes of cancer death in women in developed countries included breast and colorectal cancer; other leading causes of cancer death in men in developed countries included colorectal and prostate cancer. In less developed countries, liver and stomach cancer were other leading causes of cancer death for men, and cervical cancer was another leading cause of cancer death for women.

The study authors reported that incidence for all cancers combined is nearly twice as high in developed countries compared with less developed countries, but that cancer death rates are only 8% to 15% higher in developed countries. The authors said the disparity may be due to regional differences in cancer type, which is in turn affected by risk factors and detection methods.

"A substantial portion of cancer cases and deaths could be prevented by broadly applying effective prevention measures, such as tobacco control, vaccination, and the use of early detection tests," the study authors wrote.

1. Torre LA, Bray F, Siegel RL, et al. Global cancer statistics, 2012 [published online ahead of print February 4, 2015]. *CA Cancer J Clin*. doi:10.3322/caac.21262.

## Drug for ER+, HER2- Breast Cancer Approved

The US Food and Drug Administration (FDA) approved palbociclib (Ibrance, Pfizer) for treatment of metastatic breast cancer in postmenopausal women, according to a press release.

Palbociclib inhibits cyclin-dependent kinases 4 and 6, which are involved in promotion of the growth of cancer cells. The drug is intended for women with estrogen receptor (ER)–positive, human epidermal growth factor receptor 2 (HER2)–negative metastatic breast cancer

who have not yet received an endocrine-based therapy. Palbociclib is to be used in combination with letrozole (Femara, Novartis), another FDA-approved drug, to treat specific cancers.

The drug's efficacy was demonstrated in 165 postmenopausal women with ER-positive, HER2-negative metastatic breast cancer who had not received previous treatment for advanced disease. Patients were randomized to receive palbociclib in combination with letrozole or letrozole monotherapy. Patients in the combination therapy group had 20.2 months of progression-free survival; patients in the monotherapy group had 10.2 months of progression-free survival.

## FDA Commissioner Stepped Down

Margaret A. Hamburg, MD, has resigned her post as Commissioner of the FDA. Dr. Hamburg announced her decision in a letter to FDA employees.

In the letter, Dr. Hamburg noted that during her 6-year tenure, the FDA expedited new drug approvals via the acceleration of review for drugs designated as breakthrough therapies, and said that many novel drug approvals in the past year were approved on or before their PDUFA dates. She also cited new oversights for human drug compounding as a success of her tenure.

Stephen Ostroff, MD, Chief Scientist at the FDA, will serve as Acting Commissioner.

## FDA Approved First Biosimilar Product, Indicated for Leukemia

The FDA approved the biosimilar filgrastim-sndz (Zarxio, Sandoz), according to a press release. It is the first biosimilar approved by the FDA.

Filgrastim-sndz is biosimilar to filgrastim (Neupogen, Amgen) and is approved to treat patients with leukemia. In this instance, the FDA refers to filgrastim as a "reference product," as it is the product with initial approval.

According to the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), which was passed as part of the PPACA, the FDA can approve a biosimilar product if the product has the same mechanism of action, route of administration, and dosage forms and strengths as the original drug. Biosimilars may be approved only for indications found on the label of the reference product.

An FDA press release noted that filgrastim-sndz has been approved as a biosimilar, not as an interchangeable product. The BPCI Act states that a biological product approved as an interchangeable product does not require intervention from a health care provider who prescribed the reference product; use of biosimilars in lieu of a reference product, however, requires a health care provider's authorization.

## Study: Retinal Biomarker May Predict Parkinson Disease

Patients with Parkinson disease had thinner ganglion cell inner plexiform layers compared with patients without the disease, according to a presentation at the North American Neuro-Ophthalmology Society 2015 Annual Meeting. Medscape first reported the story.[1]

Researchers at the Prasad Centre of Ophthalmic Sciences at the All India Institute of Medical Sciences in Delhi compared patients (n = 20) diagnosed with idiopathic Parkinson disease with control patients (n = 20). Analysis of patients' retinas with spectral-domain optical coherence tomography demonstrated that patients with Parkinson disease had thinner ganglion cell inner plexiform layers than those in the control group ($P$ = .001). Contrast sensitivity was lower in the Parkinson group than in the control group ($P$ = .001)

The researchers noted that these biomarkers cannot be used to diagnose Parkinson disease, as other conditions may produce similar findings in retinal anatomy and function.

1. Harrison L. Retina changes may predict Parkinson's course. MedScape. March 5, 2015. http://www.medscape.com/viewarticle/840971

## Therapy to Improve Glycemic Control in Diabetes Approved

The FDA has approved the long-acting basal analogue insulin glargine injection (Toujeo, Sanofi) to improve glycemic control in adults with type 1 or 2 diabetes, according to a press release.

The drug was approved following a series of international phase 3 studies evaluating the drug's efficacy and safety in patients with type 1 or 2 diabetes. In the trials, the drug was compared with another insulin glargine injection (Lantus, Sanofi). The most common adverse events observed in the trials, excluding hypoglycemia, were nasopharyngitis and upper respiratory tract infection.

The drug will be available starting in the second quarter of 2015. ■

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