

# Internal Medicine News

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VOL. 43, No. 6

The Leading Independent Newspaper for the Internist—Since 1968

APRIL 1, 2010

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## New Data Challenge 130 mm Hg As Systolic BP Target in Diabetes

BY MITCHEL L. ZOLER

ATLANTA — The official U.S. guideline that patients with diabetes should receive treatment to a blood pressure target of less than 130/80 mm Hg became suspect following reports from a pair of large studies showing no benefit in these patients beyond a goal systolic pressure of less than 140 mm Hg.

In a controlled trial with more than 4,700 U.S. patients with type 2 diabetes randomized to an intensive antihypertensive regimen with a goal systolic pressure of less than 120 mm Hg or to a standard-therapy arm aiming for less than 140 mm Hg, “the results provided no conclusive evidence that the intensive blood pressure control strategy reduces the rate of a composite of major cardiovascular disease events,” Dr. William C. Cushman said at the annual meeting of the American College of Cardiology.

“We were surprised by the findings” from the Action to Control Cardiovascular Risk in Diabetes (ACCORD) blood pressure trial, said Dr. Cushman, chief of the preventive medicine section at the VA Medical Center in Memphis. “The evi-



Intensive blood pressure control did not reduce the rate of major cardiovascular disease events in patients with diabetes, Dr. William C. Cushman reported.

dence supports less than 140 mm Hg. There generally was thinking that if you're dealing with [high cardiovascular risk], such as patients with diabetes, it makes sense that their goal pressure should be more intense.” The results

“clearly say that we can't think that way anymore” and should influence recommendations expected in about a year from the Eighth Report of the Joint National Committee on the Prevention, Detec-

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## Physicians Consider Benefits, Challenges of Health Reform Law

BY MARY ELLEN SCHNEIDER

After more than a year of heated debate on the merits of health reform, policy makers and physicians are switching gears, assessing the impact of the new law and considering how to improve it in the future.

“This legislation improves the chance that our patients can see doctors,” said Dr. Frederick E. Turton, chair of the board of regents of the American College of Physicians. “When patients see their doctors, they live longer and live happier lives.”

Dr. Turton also lauded the law's provisions on preventive services, which will allow patients with Medicare, Medicaid, and private insurance to get many preventive services without incurring out-of-pocket costs. But the legislation does not go far enough in supporting primary care, he said. The 10% Medicare bonus payment to primary care physicians over 5 years is a positive feature of the new law, but much more is needed. “We're facing a crisis shortfall of primary care doctors, and 10% is not enough to make any difference whatsoever,” said Dr. Turton, a general internist in Sarasota, Fla.

**The planned Independent Payment Advisory Board ‘could result in misguided payment cuts.’**

President Obama signed most of the health reform provisions into law on March 23. On March 30, the president signed a smaller bill—known as the reconciliation bill—that Congress had passed to make adjustments to the original package, including the addition of more subsidies for purchasing insurance, and removal from the law of some of the more controversial political deals.

The new law clears the way for about 32 million previously uninsured Americans to have access to health insurance in the next few years. The law requires in-

See **Reform Law** page 6

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# Primary Care Payments to Rise

Reform Law from page 1

dividuals to obtain health coverage and creates a health insurance exchange where individuals can shop for policies that meet minimum coverage standards. The law also bars insurers from discriminating against people based on gender or preexisting medical conditions.

Of special interest to primary care physicians, Medicaid payments will be increased to the level of Medicare payments for primary care physicians delivering primary care services in 2013 and 2014. And in 2011-2016, Medicare bonus payments of 10% will go to family physicians, general internists, geriatricians, and pediatricians whose Medicare charges for office, nursing home, and home visits make up at least 60% of their total Medicare charges. The law also increases funding for community health centers.

The law's emphasis on primary care is a good start, said Dr. Neil Calman, president and CEO of the Institute for Family Health and a clinical professor of family medicine at Albert Einstein College of Medicine, both in New York.

The new focus on prevention and wellness is a much better way to advance primary care, he said, compared with the gatekeeper model that was tried over a decade ago. "That was a model where primary care was getting a boost from something that flew in the face of what consumers wanted," Dr. Calman said. The new approach is "completely consistent with what consumers want, which is well-coordinated, comprehensive care."

The new law will help Medicare beneficiaries who fall into the Medicare part D prescription drug "doughnut hole." This year, beneficiaries who enter the doughnut hole will get a \$250 rebate. Next year, drug companies will be required to provide a 50% discount on brand-name drugs paid for while the patient is in the doughnut hole, rising to 75% on both brand-name and generic drugs by 2020.

"That doughnut hole is something that you talk about every day with your patients," Dr. Turton noted.

The law also includes additional insurance protections. The federal government will require health plans to provide coverage for nondependent children up to age 26 years within 6 months of the law's enactment. The law also bars group health plans from excluding adult patients on the basis of preexisting conditions starting in 2014; for children, plans are barred from imposing such exclusions 6 months after enactment.

The law also aims to bring transparency to relationships between pharmaceutical companies and physicians and hospitals.

Under the incorporated Physician Payments Sunshine Act, sponsored by Sen. Chuck Grassley (R-Iowa) and Sen. Herb Kohl (D-Wis.), makers of medical supplies, pharmaceuticals, biologicals, and devices must report any payments or transfers of value worth more than \$100/year that they make to physicians and hospitals, starting in 2013. Manufacturers will also have to report any and

all physician ownership stakes. The Health and Human Services department will be required to make this information available to the public.

Finally, starting in 2012, manufacturers will also have to report to the HHS all the drug samples they give to physicians, if the drugs are covered by Medicare or Medicaid.

During the course of final debate, no Republican member of Congress voted

in favor of passing the bills. Republicans railed against the package as bloated and unaffordable at the Congressional Budget Office estimated price tag of \$940 billion over 10 years, despite CBO assurance that the legislation also would reduce the deficit by \$143 billion over the same period.

Republican opponents also said the legislation gave the federal government too great a role and would interfere with the relationship between patients and their doctors.

The bills were supported by the American Medical Association and other

physician organizations. AMA president Dr. J. James Rohack said that the legislation would do many good things, such as improve health by expanding coverage to millions of uninsured Americans, eliminate denials based on preexisting conditions, provide bonus payments to primary care physicians and general surgeons, and fund pilot projects on ways to resolve medical liability claims.

However, Congress still has work to do on some provisions, especially the one that establishes an Independent Payment Advisory Board (IPAB), the AMA said. The 15-member IPAB, which is set

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#### Indication

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#### Hypotension

Volume depletion and/or salt depletion should be corrected in patients before initiation of therapy or start treatment under close medical supervision with a reduced dose, otherwise symptomatic hypotension may occur. Observe patients with severe aortic stenosis closely for acute hypotension when administering amlodipine.

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In patients with impaired hepatic function, initiate telmisartan at low doses and titrate slowly, or initiate amlodipine at 2.5 mg. The lowest dose of TWYNSTA is 40/5 mg; therefore, initial therapy with TWYNSTA is not recommended in hepatically impaired patients.

#### Renal Impairment

Monitor carefully in patients with impaired renal function, especially in patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system (RAAS) (eg, patients with severe congestive heart failure or renal dysfunction); treatment of these patients with ACE inhibitors and ARBs has been associated with oliguria and/or progressive azotemia and, rarely, with acute renal failure and/or death. In patients with unilateral or bilateral renal artery stenosis, increases in serum creatinine or blood urea nitrogen may occur.

#### Dual RAAS Blockade

When adding an ACE inhibitor to an ARB, monitor renal function closely. Use of telmisartan with ramipril is not recommended.

#### Other

Uncommonly, increased frequency, duration, and/or severity of angina or acute myocardial infarction have developed in patients treated with calcium channel blockers, particularly patients with severe obstructive coronary artery disease. Closely monitor patients with heart failure.

#### Adverse Events

In clinical trials, the most commonly reported adverse events with TWYNSTA that were more frequent than with placebo were peripheral edema (4.8% vs 0%), dizziness (3.0% vs 2.2%), clinically meaningful orthostatic hypotension (6.3% vs 4.3%), and back pain (2.2% vs 0%).

#### Special Populations

In clinical studies, the magnitude of blood pressure lowering with TWYNSTA in black patients approached that observed in non-black patients, but the number of black patients was limited. TWYNSTA is not recommended as initial therapy in patients who are 75 years or older, or who are hepatically impaired. In nursing mothers, nursing or TWYNSTA should be discontinued.

References: 1. Twynsta Pl. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; 2009. 2. Data on file, Study 1235.1, Boehringer Ingelheim Pharmaceuticals, Inc. 3. Chobanian AV, Bakris GL, Black HR, et al. The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. *JAMA*. 2003;289:2560-2572.

Please see Brief Summary of Prescribing Information on following pages.

to begin its work in 2014, is charged with presenting proposals to Congress that would slow the growth of Medicare and private health care spending and improve the quality of care.

The AMA said that this board needs to be overseen by Congress and have input from physicians. "The current IPAB framework could result in misguided payment cuts that undermine access to care and destabilize health care delivery," Dr. Rohack warned in a statement.

The board should be truly independent and include adequate representation from the cognitive specialties, Dr. Turton said. ■

MY TAKE

## Facing the Challenge of Changing a Fragmented System

Given the unsustainable nature of the U.S. health care system, change was inevitable. The reform legislation starts a process of rethinking how health care can be more effective, efficient, and sustainable.

Change, however, is and will be disruptive and disconcerting. with somewhat different variables.



Managing the reform process will not be easy as patients, providers, and advocates deal with uncertainty and resource allocation in an era of financial limitations. The key issue to keep in mind is that doing nothing would soon bring on similar stress, but

How we harmonize professional activities in a fragmented health care system may turn out to be the predominant theme during the next few years.

WILLIAM E. GOLDEN, M.D., is professor of medicine and public health at the University of Arkansas, Little Rock. He reported no relevant conflicts of interest.



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<sup>†</sup>According to the JNC 7, Stage-1 hypertension is defined as 140-159 mmHg SBP or 90-99 mmHg DBP. Stage-2 hypertension is  $\geq 160$  mmHg SBP or  $\geq 100$  mmHg DBP.<sup>3</sup>

<sup>2</sup>Standard deviation was 11.9/7.6 mmHg, TWYNSTA 40/5 mg; 13.2/7.9 mmHg, TWYNSTA 40/10 mg; 12.7/8.5 mmHg, TWYNSTA 80/5 mg; 14.2/7.9 mmHg, TWYNSTA 80/10 mg; 16.7/9.4 mmHg, placebo.<sup>2</sup>

ARB: Angiotensin receptor blocker. CCB: Calcium channel blocker. DBP: Diastolic blood pressure. SBP: Systolic blood pressure. JNC 7: The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.

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