Bridging the gap among payer, provider, and patient perspectives

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THE AMERICAN JOURNAL OF MANAGED CARE®

Evidence-Based Diabetes Management

PATIENT-CENTERED DIABETES CARE 2016 | APRIL 7-APRIL 8, 2016 | TEANECK, NJ

EXCLUSIVE COVERAGE!

PC DC Patient-Centered Diabetes Care® 2016

HIGHLIGHTS FROM THE MEETING

SP321 Keynote speaker LONNY REISMAN, MD, on how data could speed care delivery and scientific findings

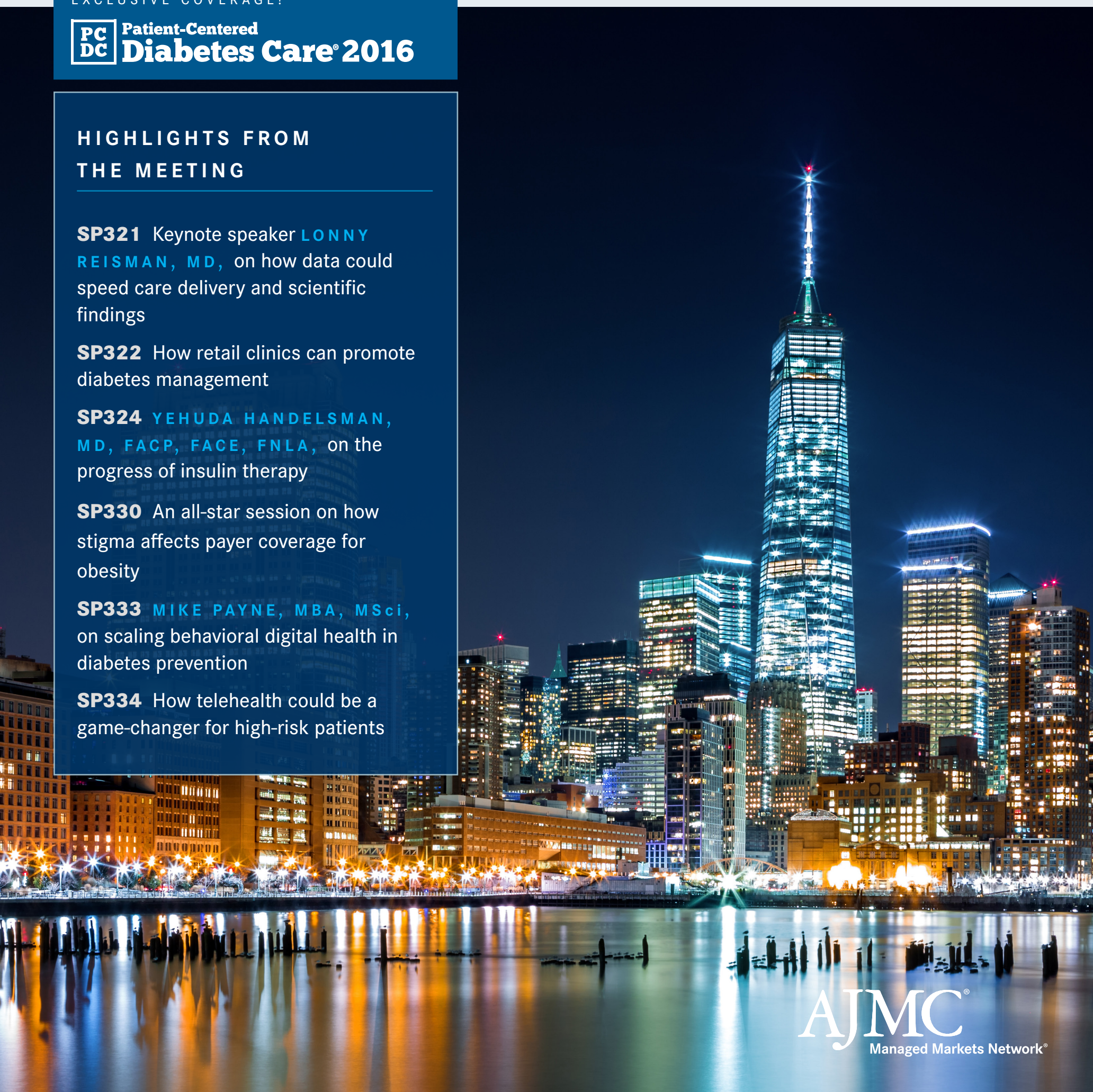
SP322 How retail clinics can promote diabetes management

SP324 YEHUDA HANDELSMAN, MD, FACP, FACE, FNLA, on the progress of insulin therapy

SP330 An all-star session on how stigma affects payer coverage for obesity

SP333 MIKE PAYNE, MBA, MSci, on scaling behavioral digital health in diabetes prevention

SP334 How telehealth could be a game-changer for high-risk patients



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SP335

From left, Dennis P. Scanlon, PhD; Robert A. Gabbay, MD, PhD, FACP; John A. Johnson, MD, MBA; Michael Gardner, MD; and Zachary Bloomgarden, MD, take part in the peer exchange, Cardiovascular Mortality in Type 2 Diabetes, which took place ahead of Patient-Centered Diabetes Care April 7, 2016.

Patient-Centered Diabetes Care Shows *AJMC* Is Ahead of the Curve

We present our annual issue with full coverage of the April 7-8, 2016, Patient-Centered Diabetes Care meeting. The conference in Teaneck, New Jersey, represented a major step in bringing forward attendees'—and now readers'—discussions on the most current topics in management of this chronic disease. A challenge, for any meeting of this type, is to foresee which topics will be timely when the moment arrives: This year, *The American Journal of Managed Care* and our partner, Joslin Diabetes Center, exceeded expectations. Multiple speakers, including Omada Health's Mike Payne, MBA, MSc, addressed the decision by Medicare to fund the Diabetes Prevention Program, an announcement that took place 2 weeks before the meeting.

Our keynote speaker, Lonny Reisman, MD, offered a detailed account of how Big Data can change the research and treatment paradigm just a week after FDA Commissioner, Robert Califf, MD, proposed these solutions at the American College of Cardiology. Our session on obesity discussed the ongoing challenges of coverage for this disease when stigma still permeates thinking among both payers and providers. As we go to press, the American Association of Clinical Endocrinologists has issued clinical practice guidelines for the treatment of obesity and the American Diabetes Association has concurred with recommendations that "metabolic surgery," long thought of as a treatment for extreme obesity, is also appropriate for less overweight patients who also have diabetes.


MIKE HENNESSY, SR

The conference also featured clinical updates from leaders in the diabetes care and research, as well as discussions on how the retail clinic can offer new solutions for care delivery. As always, the most important feature of Patient-Centered Diabetes Care was its multi-stakeholder approach: bringing together payers, providers, the pharmaceutical industry, and policy leaders to find solutions in formal and informal settings. Please enjoy the coverage of our meeting—but most of all, make plans to join us next year at Patient-Centered Diabetes Care 2017.

Sincerely,

Mike Hennessy, Sr
CHAIRMAN AND CEO

EDITORIAL MISSION

To present policy makers, payers, and providers with the clinical, pharmacoeconomic, and regulatory information they need to improve efficiency and outcomes in diabetes.

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AGENDA

THURSDAY, APRIL 7, 2016

11:00 - 1:00 PM	**Peer Exchange Filming — Reducing Cardiovascular Mortality in Patients With Type 2 Diabetes Mellitus**
3:30 - 9:00 PM	**REGISTRATION**
4:30 - 6:00 PM	**Session 1: Extending the Reach of Diabetes Care**

- The Impact of Retail Clinics on Population Health
- Collaborative Diabetes Medication Management: Advanced Practice Clinicians Working With Pharmacists
- **Panel Discussion**—Paying for Collaborative Care
  Heather Zacker, MS

6:00 PM - 7:00 PM	**BREAK**
7:00 PM - 9:00 PM	**NETWORKING RECEPTION**

FRIDAY, APRIL 8, 2016

6:30 - 2:00 PM	**REGISTRATION**
7:15 - 8:00 AM	**BREAKFAST**
8:00 - 8:45 AM	**Keynote: State of Big Data in Diabetes** Lonny Reisman, MD
8:45 - 10:15 AM	**Session 2: Clinical Management Updates**

- Insulin Management: Today and Tomorrow
- Options and Opportunities to Reduce CV Risk in T2D
- **Panel Discussion**—Paying for Adherence: Measuring Short-Term vs Long-Term ROI

10:15 - 10:30 AM	**BREAK**
10:30 - 12:00 PM	**Session 3: Obesity**

- Obesity as a Disease Turns 2 Years Old, So How Do We Celebrate?
- Measuring the Impact of Improved Coverage of Obesity Treatments
- **Panel Discussion**—Overcoming Barriers to Access

12:00 - 12:30 PM	**BREAK**
12:30 - 1:30 PM	**Lunch Symposia**
1:30 - 1:45 PM	**BREAK**
1:45 - 3:15 PM	**Session 4: Technology and Innovation**

- The Impact of EHRs and Teamwork on Diabetes Care Quality
- Democratizing Diabetes Prevention: Creating Value by Scaling Digital Behavioral Medicine
- **Panel Discussion**—Telehealth in Diabetes Care

3:15 PM - 3:30 PM	**Closing Remarks/ Adjournment**

FACULTY BIOS

CHAIR

Robert Gabbay, MD, PhD, FACP

Chief Medical Officer and Senior Vice President
Joslin Diabetes Center
Associate Professor of Medicine
Harvard Medical School
Boston, MA

Dr Gabbay is Chief Medical Officer and Senior Vice President at Joslin Diabetes Center. His research focuses on improving primary care healthcare delivery to enhance diabetes outcomes and patients' experiences. He served as faculty chair of Pennsylvania's statewide Chronic Care Model–focused Patient-Centered Medical Home (PCMH) initiative (Chronic Care Initiative), involving more than 150 primary care practices with support from 17 payers. He was also principal investigator on 2 Agency for Healthcare Research and Quality (AHRQ)-funded PCMH projects before coming to Joslin. The first project studied the experiences of 25 practices in the first regional rollout of the Pennsylvania initiative in southeast Pennsylvania. For the second study, AHRQ selected Dr Gabbay to develop state-level infrastructure for primary care transformation under AHRQ's Infrastructure for Maintaining Primary Care Transformation program. Pennsylvania was 1 of 4 states selected for this initiative aimed at laying the foundation for a nationwide primary care extension service.

At Joslin, Dr Gabbay's focus is to foster innovation within its walls, as well as disseminating these approaches regionally, nationally, and internationally. He is dedicated to creating a model for the patient-centered medical neighborhood for diabetes—a compliment to his PCMH research. The medical neighborhood will ensure patient-centered coordinated care among the team of health professionals that are required to meet the patient's needs. He is also committed to providing the best quality possible to our patients with diabetes while exceeding the highest national clinical quality measures. He also serves as editor-in-chief of *Evidence-Based Diabetes Management*.

KEYNOTE SPEAKER

Lonny Reisman, MD

Chief Executive Officer
HealthReveal
New York, NY

Dr Reisman is the founder and chief executive officer of HealthReveal, a start-up that seeks to leverage advanced data analytics and biomonitoring for early detection, as well as diagnostic and treatment guidance to preempt the advance of disease. Previously, Dr Reisman served as Aetna's chief medical officer for 6 years. During his tenure at Aetna, he was responsible for the company's clinical strategy to improve the health of Aetna's members and helped build a better healthcare system supported by evidence-based accountability by every participant. He led healthcare system change through Aetna's clinical thought leadership, Innovation Labs, clinical policy, and integrated system design.

Dr Reisman is a recognized leader in health information technology, patient safety, and evidence-based medicine, and has published numerous clinical, peer-reviewed articles. He emphasizes that issues related to cost and quality must be addressed by supporting greater adherence to evidence-based standards of care. By replacing traditional information silos, Dr Reisman has focused on new ways for information to be easily used and shared throughout the healthcare system. He is a member of the Harvard Medical School Health Care Policy Committee; the New York eHealth Collaborative Board of Directors; the RCHN Community Health Foundation, Inc, Board of Directors; and the East Coast CMO Executive Summit Committee.

MODERATOR

David Brumley, MD, MBA

Senior Medical Director
Tufts Health Plan, Inc
Watertown, MA

Dr Brumley is a board-certified family practitioner who has many years of managed care, clinical, and consulting experience. His current responsibilities at Tufts Health Plan include various clinical and utilization management programs, supporting sales and network contracting, providing clinical pharmacy support, and acting as the primary liaison to Patient-Centered Medical Home and care transformation initiatives in Massachusetts and Rhode Island. Prior to Tufts Health Plan, he served as senior medical director at Blue Cross Blue Shield of Rhode Island and as medical director at Blue Cross Blue Shield of Massachusetts. He has also served as senior vice president of consulting for Medical Scientists, Inc, and as senior medical director for Oxford Health Plans.

Dr Brumley serves on the editorial board of the *Population Health Management* journal. He has held several leadership roles in the Blue Cross Blue Shield Association and the Care Continuum Alliance, and has served on National Committee for Quality Assurance expert panels in measurement development. He has also served in clinical roles at St. Joseph Family Medical Center in Nashua, New Hampshire; Manet Community Health Centers in Quincy, Massachusetts; and the Rhode Island Free Clinic in Providence, Rhode Island.

FACULTY

Scott Breidbart, MD, MBA

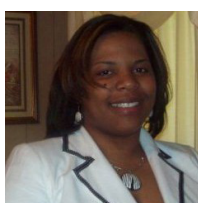
Chief Clinical Officer
EmblemHealth
New York, NY

At EmblemHealth, Dr Breidbart is responsible for the clinical aspects of all lines of business, including Medicare, Medicaid, Marketplace plans, and commercial. His prior work in managed care included consulting for Oxford Health Plans and employment at Health Net and Empire BlueCross BlueShield. His responsibilities have been in the areas of utilization management, case and disease management, wellness, medical policy, medical analytics, quality, and the clinical aspects of provider and public relations, value-based contracting, medical homes, and claims policies.

Dr Breidbart has been the America's Health Insurance Plans (AHIP) liaison member to the National Vaccine Advisory Committee since 2013. In that role, he has worked with AHIP and other stakeholders to improve the delivery of vaccines. He also serves on the editorial advisory boards of *Value-Based Cancer Care* and *Value-Based Care in Rheumatology.*

Tearsanee Carlisle Davis, DNP, APRN-BC

Lead Nurse Practitioner
University of Mississippi Medical Center
Center for Telehealth
Jackson, MS



Dr Davis is the lead nurse practitioner for the Center for Telehealth at the University of Mississippi Medical Center. In addition to representing the center at various professional organizational meetings, she is responsible for the clinical oversight of the school and corporate telehealth programs, management of advanced practice providers, and program development and implementation. Dr Davis serves as co-coordinator, curriculum developer, content developer, and instructor for the training program. With over 18 years of nursing experience, she has worked in various healthcare settings, including private practice, community health, emergency medicine, and academia.

Dr Davis is a member of numerous professional organizations and participates on committees that promote the profession of nursing; she takes great joy in mentoring young nurses. She is the principal investigator for the Mississippi Diabetes Telehealth Network pilot project.

Kristene Diggins, FAANP, CNE, NEA-BC, DNP, MBA

Manager of Professional Practice
MinuteClinic
Waxhaw, NC

Dr Diggins is a corporate senior educator for MinuteClinic, as well as adjunct faculty for LibertyNew University and the University of Phoenix. She has 10 years' experience in direct patient care, in both family practice and geriatrics. She earned the Diplomat of Comprehensive Care certification from the American Board of Comprehensive Care. She also earned her MBA and the distinctions of a Nurse Executive Advanced certification and Certified Nurse Educator from the American Nurses Credentialing Center.

Dr Diggins is a leader in retail healthcare leadership through training and administration of nurse practitioners and physician assistants. Her current position involves development and leadership of the practice of clinicians in the convenient care industry. She is an active volunteer and has served in developing countries. As a freelance author, she writes regular columns on health for various nursing journals.

Jeffrey Farber, MD, MBA, FACP, CPE

Chief Executive Officer
Mount Sinai Care LLC
Senior Vice President and Chief Medical Officer, Population Health
Mount Sinai Health System
New York, NY

Dr Farber received his medical degree with AOA honors from the Albert Einstein College of Medicine of Yeshiva University. He completed a residency in Internal Medicine at New York Presbyterian Hospital, Columbia Campus, and a fellowship in Geriatric Medicine at Mount Sinai School of Medicine.

His career interests include research in models of care for older adults, as well as clinical documentation quality and the medical interface with healthcare finance. He is a recipient of a federal Geriatric Academic Career Award, and his research has been published in *The Annals of Internal Medicine* and *The Journal of Hospital Medicine*. He is the chief executive officer of Mount Sinai Care, LLC, the accountable care organization of the Mount Sinai Health System; his role in population health gives him responsibility for quality, utilization, clinical integration, physician engagement, care management, clinical programs, and practice transformation.

Ilana Graetz, PhD

Assistant Professor
Health Services and Policy Research Department of Preventive Medicine
University of Tennessee Health Science Center
Memphis, TN

Dr Graetz's research work focuses on patient knowledge and behavior with respect to insurance access and insurance benefit design, and the role of health information technology and organizational culture and their effects on clinical care quality and costs for patients with chronic conditions. She is particularly interested in how technology can be leveraged to improve care and self-management practices for patients with diabetes.

Dr Graetz's graduate-level work in the area of organizational theory was awarded an Agency for Healthcare Research and Quality–sponsored dissertation grant to examine the relationship between use of electronic health records, care coordination, and care quality and outcomes for patients with diabetes. Prior to her current position, she worked as a data analyst at the Division of Research at Kaiser Permanente Northern California (in Oakland) for nearly 10 years.

Yehuda Handelsman, MD, FACP, FACE, FNLA

Medical Director and Principal Investigator
Metabolic Institute of America
IP-President
American College of Endocrinology
Tarzana, CA

Dr Handelsman is the medical director and principal investigator of the Metabolic Institute of America; an endocrinologist in solo private practice in Tarzana, California; and the immediate past president of the American College of Endocrinology (ACE). He developed and successfully utilizes a comprehensive, multiple-intervention approach to preventing and managing diabetes, obesity, lipid disorders, and cardiovascular disease. A fellow of the American Association of Clinical Endocrinologists (AACE), American College of Physicians, and National Lipid Association, he has been listed repeatedly in "Top Doctors of Los Angeles," "Southern California Super Doctors," "The Leading Physicians of the World," and "Best Doctors of America."

Besides ACE, Dr Handelsman is a past president of the AACE; chair of the AACE Diabetes and Lipid Scientific Committees; a member of the Obesity Scientific Committee; co-chair of AACE/ACE Scientific & Clinical Review: Association of SGLT2 Inhibitors and DKA; chair and program director of the Annual World Congress on Insulin Resistance, Diabetes & Cardiovascular Disease; chair and founder of the International Committee for Insulin Resistance and the International Lipid Forum; and Treasurer of the Pacific Lipid Association.

Dr Handelsman is an associate editor of the *Journal of Diabetes* and a member of the editorial panel of *European Medical Journal—Diabetes*, editorial advisory board for *Clinical Endocrinology News*, and editorial board for *Endocrine Today*. His book, *Clinical Management of Cardiovascular Risk in Diabetes and Obesity*, was published by Professional Communications, Inc, in 2016.

Janine Kyrillos, MD, FACP

Director, Comprehensive Weight Management Program at Bala
Thomas Jefferson University
Philadelphia, PA

Dr Kyrillos is board-certified in both Internal Medicine and Obesity Medicine and is the director of the Comprehensive Weight Management Program at Jefferson. She has been a primary care physician for 14 years, focusing on the medical management of patients affected by obesity and being overweight. She now has a practice dedicated to obesity and works closely with the bariatric surgery program at Jefferson.

Dr Kyrillos began her career as a nurse after receiving her bachelor's degree from the University of Pennsylvania. She earned her medical degree from Robert Wood Johnson Medical School and

returned to Philadelphia to complete her Internal Medicine residency at Thomas Jefferson University Hospital. She pursued independent study to earn her board certification from the American Board of Obesity Medicine in 2013. She has authored/coauthored articles and book chapters on obesity and medical management of the surgical patient.

Ted Kyle, RPh, MBA

Founder and Principal
ConscienHealth
Pittsburgh, PA

Mr Kyle is one of the country's most influential advocates calling for equity and evidence-based approaches to the treatment of obesity. A pharmacist with experience in the pharmaceutical industry, he founded ConscienHealth in 2009 to collaborate with leading health and obesity experts for sound policy and innovation to address obesity. Mr Kyle chairs the board of directors for the Obesity Action Coalition, advises The Obesity Society on advocacy, and consults with companies seeking to address the needs of individuals classified as obese. His widely read daily commentary, published at ConscienHealth .org, reaches an audience of more than 10,000 thought leaders in health and obesity.

Cathleen McKnight, DNP

Director, Patient Centered Strategies
The Little Clinic
Nashville, TN

Dr McKnight is a family nurse practitioner and currently serves as the director of Patient Centered Strategies for The Little Clinic, located inside select Kroger Company stores. In her role, she is responsible for clinician education, scope of services, affiliations, and political advocacy. Her focus areas include primary care and quality improvement strategies. Dr McKnight is board-certified with the American Academy of Nurse Practitioners. She is also a member of Sigma Theta Tau International Honors Society and a recipient of the Sigma Theta Tau 2010 Honorary Award.

Dr McKnight presents locally and internationally to an array of audiences. She currently serves as adjunct faculty for doctoral nursing students, is on the editorial board for *Contemporary Clinic*, and serves as a key person for the Ohio Association of Advanced Practice Nurses' political initiatives. Dr McKnight's work fulfills The Little Clinic's mission to offer America's most convenient and accessible delivery of affordable health and wellness care for the whole family.

Joanna Mitri, MD, MS

Clinical Investigator
Joslin Diabetes Center
Boston, MA

Dr Mitri obtained her MD degree in Lebanon and completed her training in the Advanced Endocrinology, Diabetes & Metabolism Fellowship at Tufts Medical Center. During her training, she received a full scholarship to enroll in the master's program in Clinical and Translational Science at Tufts University. During her career, Dr Mitri has published her research findings in high-impact peer-reviewed journals. Her major clinical interest is cardiovascular disease prevention in patients with diabetes. Dr Mitri is a staff physician in the Adult Diabetes Section and a research associate in the Section on Clinical, Behavioral, and Outcomes Research at the Joslin Diabetes Center, and a clinical instructor at Harvard Medical School. She is currently working on consolidating the cardiometabolic program at Joslin.

Eileen Myers, MPH, RDN

Vice President, Retail Dietetics & Nutrition Solutions
The Little Clinic
Nashville, TN

Ms Myers is the vice president of Retail Dietetics & Nutrition Solutions for The Little Clinic, a retail healthcare company operating over 180 clinics inside Kroger grocery stores. She is responsible for successful execution of nutrition services in the clinics and stores; she also works with leadership on overall prevention and wellness services in close proximity with Kroger health and wellness initiatives. Previously, she was responsible for creating and developing clinical partnerships across the healthcare industry for The Little Clinic.

Ms Myers is a board member of the Convenient Care Association and is a coauthor of the chapter, Collaboration and Partnership in the Convenient Care Setting in the 2013 book, *Convenient Care Clinics: The Essential Guide for Clinicians, Managers, and Educators*, a Springer publication. She also published a book by Helm Publishing, *Winning the War Within: Nutrition Therapy for Clients with Eating Disorder*, a teaching manual for clinicians working in the field of eating disorders (in print from 1999-2016).

Mike Payne, MBA, MSci

Chief Commercial Officer
Head, Medical Affairs
Omada Health
San Francisco, CA

Mr Payne is a leader who has worked with companies in almost every sector of healthcare and health technology. He believes that small companies with new ideas can change healthcare, but only if they work hand-in-hand with current leaders in the industry. Mr Payne is committed to continuing Omada's leadership among a new generation of health providers focused on evidence-based digital behavioral medicine programs for specific and complex—but preventable—chronic conditions. He joined Omada from biotechnology leader Gilead Sciences, where he spent 6 years as a commercial strategy exeuctive with experience in new product development, mergers and acquisitions, and marketing. Mr Payne was previously with the healthcare practice at McKinsey & Company, where he worked with healthcare clients in biotechnology/pharma, medical devices, health systems, and global health. He also spent time with Accenture's Strategy Group working with enterprise technology clients. Mr Payne has an MBA from Stanford Business School, as well as an MS degree in Health Services Research from Stanford Medical School.

S. Sethu Reddy, MD, MBA, FRCPC, FACP, MACE

Chief, Adult Diabetes
Joslin Diabetes Center
Boston, MA

Dr Reddy is past chairman of Endocrinology, Diabetes & Metabolism at Cleveland Clinic and most recently was vice president for Medical Affairs at Merck. His research interests are primarily devoted to clinical endocrinology, including obesity and thyroid disorders, and the epidemiology of diabetes and its complications. He has authored and coauthored more than 140 articles, abstracts, and book chapters concerning these and related topics. In 2009, he authored the *Cleveland Clinic Guide to Diabetes*. He has been a key sponsor of Merck's adherence initiative in the United States and was also the lead for Medical Solutions as part of the Global Customer Centricity initiative at Merck.

Dr Reddy has been actively involved in clinically relevant projects with the American Association of Clinical Endocrinologists (AACE) since 1996, including Coding & Reimbursement, Fellowship Training, Optimal Practice of Diabetes Task Force, Endocrine University Program, Socioeconomic Affairs, Minority Health Affairs, Clinical Practice Guidelines, and Academic Affairs. He has been elected twice to the national board of directors of AACE and, most recently, was elected to the board of trustees for the American College of Endocrinology. He has also been actively involved with the Endocrine Society as chair of the Corporate Liaison Committee.

Dr Reddy was honored by the Cleveland Clinic with the Florence Nightingale Award for Physician Collaboration and as Trustee of the Year in 2005 by the Diabetes Association of Greater Cleveland. In 2007, he was the recipient of the distinction of Mastership in the American College of Endocrinology.

Anne Schmidt, MD

Associate Medical Director
Blue Cross Blue Shield of Alabama
Birmingham, AL

Anne Schmidt, MD, is a graduate of Clemson University and received her MD degree from the Medical College of Georgia. She completed residency training at the University of Tennessee in Memphis and is board-certified in Family Medicine. Dr Schmidt has practiced primary care in both rural and urban settings and

has served as medical director at United Cerebral Palsy of Greater Birmingham, developing a medical home model of care for people with disabilities. She currently serves as associate medical director at Blue Cross and Blue Shield of Alabama.

Fatima Cody Stanford, MD, MPH, MPA

Obesity Medicine, Health Policy,
Obesity Medicine Physician
Instructor of Medicine and Pediatrics
Massachusetts General Hospital
Harvard Medical School
Boston, MA

At Massachusetts General Hospital, Dr Stanford is an obesity medicine physician for children, adolescents, and adults. She is an associate at the Disparities Solution Center and serves on the affiliated faculty at the Mongan Institute of Health Policy. At the MGH Weight Center, she provides behavioral, pharmacologic, and bariatric surgery pre- and postoperative care. She is one of a handful of clinicians who are fellowship-trained in Obesity Medicine in the United States. She is a diplomate of the American Board of Obesity Medicine and a fellow of The Obesity Society.

Dr Stanford received her BS and MPH degrees from Emory University, her MD degree from the Medical College of Georgia School of Medicine, and her MPA degree from the Harvard University Kennedy School of Government, where she was a Zuckerman fellow. She served as a health communications fellow at the CDC and worked as a behavioral sciences intern at the American Cancer Society. Upon completion of her MPH degree, she received the Gold Congressional Award—the highest honor that Congress bestows upon America's youth. Dr Stanford completed a medicine and media internship at the Discovery Channel and has authored a USMLE Step 1 medical review text. An American Medical Association (AMA) Foundation Leadership Award recipient in 2005 and an AMA Paul Ambrose Award winner for national leadership among resident physicians in 2009, she was selected for the AMA Inspirational Physician Award in 2015.

The American College of Physicians selected Dr Stanford as the 2013 recipient of the Joseph E. Johnson Leadership Award, an award presented to the associate member of the College who has demonstrated qualities that exemplify the College's mission "to enhance the quality and effectiveness of healthcare by fostering excellence and professionalism in the practice of medicine." Additionally, she is the 2015 recipient of the MA ACP Young Leadership Award.

Her current research focuses on obesity, health disparities, and health policy. She is widely published in peer-reviewed journals such as *Circulation* and in popular press outlets such as the *NY Times*, and has been a featured expert on numerous broadcast television outlets. She served as the keynote speaker on obesity for the AMA House of Delegates prior to their decision to acknowledge obesity as a chronic disease at their 2013 meeting.

Kristen Ratcliff-McGovern

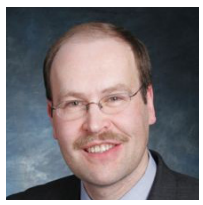
Managing Partner
Sirona Strategies
Washington, DC

Drawing on years of experience working in the presidential administration and the private sector, Ms McGovern's role is to translate policy, regulatory, and legislative developments into effective business and communications strategies. She focuses on a wide range of healthcare policy issues, including Medicare payment policy, payment and delivery system reform, health information technology (IT), and more.

She previously worked on healthcare regulatory and policy issues as an attorney at DLA Piper, advising a diverse group of healthcare clients. Before joining the private sector, Ms McGovern served as an advisor to the National Coordinator for Health IT and at the Office of Management and Budget in the Executive Office of the President. She joined the federal government through the Presidential Management Fellows program.

Albert Tzeel, MD, MHSA, FAAPL

Regional Medical Director, Senior Products
Humana
Jacksonville, FL



Dr Tzeel is Humana's regional medical director for Senior Products in north Florida. He joined Humana in March 1999 as the Humana medical director for Milwaukee. Since that time, he has also served as the market medical officer for the states of Wisconsin and Michigan and as the national medical director for HumanaOne. Dr Tzeel earned his MD degree from the University of Michigan Medical School in Ann Arbor and his MHSA degree from the University of Michigan School of Public Health, also in Ann Arbor. He also has a Certificate in Healthcare Informatics from the Drexel University College of Information Science & Technology.

A board-certified pediatrician, he has been a member of the board of the WI Family Assistance Center for Education, Training and Support, as well as a member of the board of the Juvenile Diabetes Research Foundation of southeastern Wisconsin. Dr Tzeel has also been active in the American Diabetes Association through its Camp Committee and was the 2013 co-chair for the Southeastern Wisconsin ADA Gala.

Deneen Vojta, MD

Vice President, United Health Innovation Group
Chief Clinical Officer and Executive Vice President,
Diabetes Prevention and Control Alliance
United Health Group
Minnetonka, MN

Deneen Vojta, MD, is executive vice president and chief scientific officer, Research & Development, at UnitedHealth Group. As a member of the core leadership group, she identifies innovative solutions in the marketplace that address the significant healthcare challenges facing the nation.

Dr Vojta previously served as vice president of Research and Innovation for UnitedHealthcare. Before joining UnitedHealth, she held several senior management positions in healthcare. Most recently, she served as CEO of MYnetico, a company she founded to focus on the child obesity epidemic facing the nation. Dr Vojta has 20 years of executive experience in health system and health plan administration, served as a board member of nonprofit healthcare institutions, and received numerous federal and foundation grants to investigate complex healthcare concerns. She is well published and frequently invited to speak on a number of health issues.

Heather Zacker, MS

Senior Director of Care Alliance, Joslin Innovation
Joslin Diabetes Center
Boston, MA

Ms Zacker serves as the senior director of Care Alliances in Joslin Diabetes Center's Innovation division. In this role, she leads business development, program design, and implementation of international and US alliances with healthcare providers, business enterprises, and public entities. Ms Zacker collaborates with clinical leadership in the planning and delivery of diverse programs in clinical and educational innovation across a broad range of care delivery systems, business models, industry segments, and educational platforms, and has broad administrative duties.

Her passion is to bring together resources and ideas at the juncture of public health goals and business imperatives, improving the health of patients and communities through programs that are both effective and financially sustainable. Prior to working with Joslin, Ms Zacker consulted for a variety of healthcare providers, analytics firms, and government agencies. Her work included building affiliations between hospital systems and community health centers, restructuring compensation and performance measurement systems, creating outcomes measurement tools for assessing satisfaction and costs, evaluating public health initiatives, developing value proposition positioning and market approaches, developing and disseminating knowledge on best practices, and evaluating programs to create career pathways for frontline healthcare workers.

Earlier in her career, Ms Zacker worked at Harvard Community Health Plan managing radiology and visual services in 14 staff-model health centers and developing centralized specialty care programs. She coordinated neuro-epidemiology research projects within the Framingham Heart Study and for clinical trials. Publications and presentations include book chapters, papers, and talks on managed care, managing operational resources, career pathways for healthcare workers, political analysis, and silent stroke epidemiology.

Deploying Everyday Data Into Better Diabetes Care

MARY CAFFREY

ABOUT THE KEYNOTE SPEAKER

LONNY REISMAN, MD

Dr Reisman is the founder and chief executive officer of HealthReveal.

The burden of diabetes is large: more than 29 million Americans[1] and more than 422 million people worldwide.[2] The cost of diabetes care is high and growing—it reached $97.68 per member per year in 2014, leading all other diseases for commercially insured patients covered by Express Scripts.[3]

The good news, according to Lonny Reisman, MD, formerly with Aetna and now the CEO of HealthReveal, is that diabetes has more therapeutic options than ever. The bad news? Many of these drugs are expensive, and with the flood of information on diabetes available, how is the average practitioner—especially those in primary care—to keep up?

Data can hold the key, said Reisman, who offered the keynote address, "The State of Big Data in Diabetes," which opened the April 8, 2016, session at Patient-Centered Diabetes Care, presented by *The American Journal of Managed Care* and Joslin Diabetes Center, in Teaneck, New Jersey.

Even with advances and more effective treatments for diabetes, "There are huge issues in terms of awareness and education," Reisman said, especially in addressing patient behaviors that affect the condition. As a cardiologist, Reisman sees the effects in his field: 57% of the costs of diabetes come from strokes and coronary disease.[4]

And the costs are large: a well-known study by the American Diabetes Association found that of the $176 billion in annual direct medical costs, 43% came from inpatient hospital stays. Medical spending is typically 2.3 times higher if a patient has diabetes, Reisman said.[1,5]

> **"Certainly, if we exploited the information available, we can do some pretty exciting things."**
>
> —LONNY REISMAN, MD

"Despite the advent of programs, new drugs, and diagnostic techniques, we actually do a pretty poor job," he said. If healthcare seeks to deliver better quality care, improve population health, and lower costs in diabetes care, the system is falling short. The question, Reisman asked, is "Why aren't we in a better place?"

A huge challenge, he said, is bridging the gap between new evidence and what is happening in clinical practice. Even if physicians have time to digest new studies, it is unlikely they will recall information on subgroups and exclusions for the patient sitting in front of them. At the same time, huge amounts of data are being gathered on patients each day and collected in electronic health records (EHRs), so that "machine learning" could be ongoing, he said.

To improve care at the community level, "We really need a better solution," Reisman said. "We really need to take advantage of what's available to us, to exploit all these data sources."

How can this be done? Reisman showed how today's medical information exists in silos: claims data, clinical data, data from research by pharmaceutical companies, and new, rapidly accumulating amounts of behavioral data being collected through social media. The promise of "Big Data," he said, is the hope that these data sources can be integrated and harnessed for the betterment of patients at the point of care.

"Certainly, if we exploited the information available, we can do some pretty exciting things," Reisman said. The challenge is creating "a bridge to the patient on the street."

Harnessing Big Data means figuring out how to deal with the "4 Vs": the volume of data, the variety of data sources, the velocity or constant stream of data, and the veracity or accuracy of data. If information from EHRs is mixed with nontraditional sources, steps must be taken when data are captured and interpreted to ensure they are useful for decision making.

Harnessing Big Data is based on several principles:

- Prevention is better than waiting for disease to happen.
- Advanced analytics can predict costs and adverse outcomes.
- Care can be tailored to the person.
- Large amounts of data can track population health trends.
- Technology can be used to engage patients.

Challenges involving patient privacy, standards, and fragmentation must be overcome. Some sources of data have good incentives to share it, and some do not. But when data are used well, they can reveal or confirm risk factors that can be deployed into clinical practice. Reisman pointed to a study that had just been presented at the recent meeting of the American College of Cardiology that showed how waist circumference is a more important risk factor than overall weight or body mass index for persons with diabetes.[6]

"Not everything can be done through a clinical trial," Reisman said. The study, by Intermountain Health and Johns Hopkins, is a good example of the "machine learning" that extracts patient information to gain new insights. He pointed to the well-publicized results for empagliflozin (Jardiance) from a large, very expensive randomized clinical trial that showed a cardiovascular benefit for the diabetes drug. But Reisman asked whether extrapolation of data could be used to show benefits or risks in the future for similar drugs.

The real promise, Reisman said, will come when implantable devices or wearables can be integrated with evidence-based standards for at-risk patients, and warn patients or physicians when that a patient's physiological indicators show something is going awry. These are the solutions Reisman is pursuing at HealthReveal.

"To the extent there is clear deviation from what the literature would suggest is optimal—such as a patient who's got microalbuminuria plus or minus hypertension who isn't on an ACE inhibitor—we should actually express to the treating physician, based on our current data on this patient at this moment in time, we think you might want to consider an ACE inhibitor."

"This is relatively new, but the benefits are huge," he said. **EBDM**

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CONTEMPORARY Clinic

How a Digital Tool Lets Clinic Customers Hold a Place in Line. View at http://bit.ly/1UueG33

Providing Convenient, Accessible, and Affordable Care With Retail Clinics

BRENNA DIAZ

Retail health clinics are improving access for some populations that have struggled to get care in the past, explained Eileen Myers, MPH, RDN, and Cathleen McKnight, DNP, on the first day of Patient-Centered Diabetes Care, presented April 7-8, 2016, by *The American Journal of Managed Care* and Joslin Diabetes Center.

During their presentation, Myers and McKnight examined the various steps and implementation of chronic care programs within retail clinics, retail factors that improve patient outcomes as opposed to traditional care, and how retail clinics work with health systems.

Myers began by sharing the history of The Little Clinic, one of many retail clinics whose mission is to provide family care that is convenient, accessible, and affordable. As a community-based site of care, retail clinics offer a unique variety of benefits. "We are in the retail establishments that people trust," Myers said. "We are available at the times that don't disrupt work. We utilize an electronic medical record that supports longitudinal tracking. We have health system relationships, and we have the unique opportunity to share data with pharmacy to enhance adherence."

She then elaborated on a new project of The Little Clinic, which includes dietitians on the care team. Dietitians offer medical nutrition therapy, group counseling, nutrition store tours, and cooking demonstrations, among other services. When a patient has diabetes, The Little Clinic asks the person to complete a form, and the team discusses the patient's needs and helps the patient find appropriate foods according to his or her culture, economic setting, and preferences.

Myers added that the clinics perform routine screenings, such as employer-based biometric screenings, to identify individuals at risk for diabetes. Retail clinics are able to use acute care services and physicals in order to find undiagnosed diabetes and then refer those individuals for further evaluation.

"We absolutely cannot do it alone…," she said. "That is absolutely not our case, nor do I think any of our other fellow retail clinics [can do it]. We work with health systems to help manage patients."

McKnight followed, detailing the responsibilities and characteristics of retail clinics as a whole. She described the aims of retail health as keeping people healthy, increasing engagement and wellness decisions in those that are less connected, and creating meaningful impacts in sustainable lifestyle changes for struggling individuals. Furthermore, retail health seeks not only to treat the symptoms and the diseases, but also the underlying problems of societal health. Retail clinics differ from traditional healthcare in that they provoke a preemptive healthcare model rather than a reactionary one.

"The reach of the retail clinic captures a large, potentially untapped and invisible population. Instead of the patient seeking healthcare, retail clinics are positioned to pursue community," McKnight said.

Retail health is appealing to many people who struggle with diabetes; many within the clinic's patient population do not have primary care providers (PCPs) and some who claim that they do may not be in touch with them. When these patients show up due to an acute episodic visit, it is an opportunity to reincorporate the patient back into the healthcare system. For patients with compliance issues relating to cost, convenience, or accessibility, retail clinics may be the solution, McKnight said.

She added that retail health clinics act as an outlet for the rising demand of the chronic care population, can act as economic relief, and can coordinate the appropriate level of care to the appropriate level of expertise. These clinics do have the ability to provide chronic care as they identify needs, assess patient knowledge of those needs, and then offer counseling around acute care complications. They also provide primary and secondary care including immunizations, vaccines, and programs for smoking cessation or weight loss.

McKnight pointed out that clinics unburden a clogged system and increase compliance with medication; a referral system allows PCPs and specialists to collaborate on follow-up visits, lab monitoring, and medication management. Referral partnerships also permit easy movement of patients from one site to another in order to ensure the continuity of care. **EBDM**

Collaborative and Convenient Care: *Reevaluating Approaches to Diabetes Management*

BRENNA DIAZ

Kristene Diggins, DNP, FAANP, MBA, emphasizes the importance of collaborative diabetes medication management with both pharmacists and patients, especially in convenient care settings. Patients value convenience over quality, which means that offering the option for retail care, also known as convenient care, is essential to maintaining population health.

"We can give convenience and quality, but when we think about 'what is the challenge with diabetes management?' it is the lack of convenience in caring for the multifaceted aspects of diabetes," explained Kristene Diggins, DNP, FAANP, MBA, manager of professional practice at the MinuteClinic. Diggins outlined the problem of medication adherence, a major challenge in diabetes care: approximately 40% of chronic disease medications are not refilled, because when a patient no longer experiences the symptoms that the medication targets, he or she may no longer see the need for the pill. Instead, she said, people see an opportunity to save on their grocery bill.

Convenient care settings help because they allow a patient to come in for a minor issue or a routine checkup, and physicians can tell from the electronic health record whether the patient has other chronic conditions. This presents an opportunity to discuss the condition and to better educate a patient about their treatments, according to Diggins. The physician may bring up lifestyle changes, behavior modifications, and interview the patient about what works and what does not.

Care is enhanced when it includes collaboration, and Diggins said that collaborating with pharmacists is vastly underestimated. She likes working with pharmacists because they understand the side effects, the cost effectiveness, and the best time of day to take medications. An important technique health plans should consider is pharmaceutical counseling—also known as medication management. This process allows pharmacists to recommend which medications be combined to make adherence easier for patients taking multiple medications. Pharmacists can also see which medications the patient is not refilling and explain why that medication is important. These efforts generally lead to greater compliance. Diggins cited a study from *JAMA* where one outpatient practice had a full-time pharmacist, and the hospital endorsed it because it kept admissions down.[1]

Collaborative care also means patient-centered care, in which the patient is involved in the decision making. Providers must use language patients understand. "Diabetes is complex enough for us with all of our degrees and all of our background," Diggins said. "How in the world do we

expect our patients to understand the continually changing nuances of these conditions?"

Collaborative care starts with the patient owning and understanding his or her condition, she said. Providers are partners, but the goals should be identified by the patient, not by the provider. To accommodate this way of thinking, Diggins said providers must see patients as customers. One example of this outlook is how providers approach follow-ups.

"The minute we start scheduling, what we find is we give up the core competency of convenience," she said. "So the truth is, what we have found works best is follow up by phone call." Providers can ask whether or not a patient has met with the primary care provider (PCP), and if not, recommend a PCP in the area.

Patients prefer convenient care; they are more inclined to adhere to treatments or pursue follow-up if this happens on their schedule. Diggins added that while physicians may be providing the necessary information to patients, they must make sure it is understood. Ultimately, patients make their day-to-day decisions as they interpret the information—and this can be affected by a person's culture, education, or health literacy level.

"And so no matter what setting you work in, you realize that this is a challenge," she said. "In convenient care, we know that while we list services that we're providing, that's not actually what we end up doing."

Diggins warned that Americans have become complacent toward diabetes, and this applies to both patients and clinicians. As such, it is important to reevaluate current approaches to diabetes management and how they can be made more effective. This includes a focus on a convenient care setting and involves collaboration with both pharmacists and patients. **EBDM**

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The Importance of Translating Information for Informed Decision Making

BRENNA DIAZ

Definitions of collaborative care may differ among stakeholders, but all 4 panelists taking part in a discussion at Patient-Centered Diabetes Care on April 7, 2016, focused on improving communication among care providers and patients. According to Kristene Diggins, DNP, FAANP, MBA, manager of professional practice at MinuteClinic, an important part of collaborative care is translating information so that the patient can make informed decisions.

Heather Zacker, MD, director of international programs and operations at Joslin Diabetes Center, said there are 3 other specific aspects about collaborative care:

- It is critical to augment care wherever possible, in whatever location
- Providing information is not the same as communicating, which involves not only the patient's commentary and behavior, but also his or her value system, cultural biases, and worldview
- This can happen only if the healthcare system has the right infrastructure and incentives to align these interactions.

Albert Tzeel, MD, MHSA, FAAPL, northern Florida regional medical director for senior products, Humana, explained the different models of paying for collaborative care and the recent shift toward value-based reimbursement. According to Tzeel, many markets are ready to accept full global risk; thus, it is important to ensure that they are successful both financially and in their ability to share data. He also referenced Humana's current goal of incorporating physician feedback in order to make appropriate modifications.

Jeffrey Farber, MD, MBA, FACP, CPE, chief medical officer of Mount Sinai Care, described his organization's unhappiness with the fee-for-service model and its excitement for the new value-based arrangements. With this movement toward value-based payments, there will be more freedom for innovation in care models and the ability to provide what they think patients need most, he explained.

Diggins said she would like to see employers play a greater role in incentivizing and motivating patients to see a provider. It is transparency of pricing and convenience, she said, that brings people back into care settings.

The conversation then shifted to the effects of technology on healthcare and how it could connect all those who participate in the management of a patient's diabetes. Diggins explained the importance of telehealth, especially in a convenient care setting where patients do not always have a provider who is readily accessible. She said some patients gave higher satisfaction ratings for telehealth than they did for a face-to-face encounter because they could suddenly hear how their heart sounds.

Farber discussed a new project from Mount Sinai, which is trying to recreate a hospital stay within the convenience of the home. The project includes coordinating technology, medical supplies, pharmacy, nursing, home care agencies, physical therapy, occupational therapy, social work, and care management staff for patients who struggle to leave home. Mount Sinai has even partnered with Google and Apple in order to develop apps and other devices to promote patient engagement. Joslin Diabetes Center also generated a new model of care called the Care Alliance Model, which has expanded its partnerships to include not only outpatient endocrinology spaces but also inpatient settings, primary care physician settings, and community settings.

"And so we're starting to recognize…that diabetes is not something that only takes place once every 3 months at the endocrinologist's office," said Zacker. "It's a 24/7 condition, and there are so many different components that need to work together."

However, Tzeel said that although technology can be extremely useful, it must be done well. There remain examples of low-tech, high-quality care: he discussed one of the management service organizations in Florida that uses only paper records, and it has outperformed others in its Health Examination Data and Information Set (HEDIS) results and Medicare Star ratings.

"They have a program from an access perspective," said Tzeel. "They will see pretty much any one of their diabetics 7 days a week, pretty much any time, and they will communicate. They will tell them something. They will make sure they repeat it and understand it, and they'll tell them what they said again and keep following up with them on a regular basis to ensure that it's there. And they're doing great."

In a similar vein, Diggins described the "Ask Me 3" tool, where the patient must ask 3 very basic questions at the end of a meeting with the provider, such as: why did I come? Can I repeat back what was said? What are my actions going to be afterward?

Farber said that there has been tremendous opportunity to rethink value in healthcare as the people who pay for healthcare, largely employers, are done with a system that has failed for decades. "And when you talk about paying for collaborative care, that's the beauty of it," he said. "If there's a good value proposition to whatever it is—a device, a technology, a service, a care team, a model—then there is a future for that and how to fund it."

Zacker ended the discussion by saying that it will not be a wholesale transformation of the system, that the change to value-based care is and has to be gradual, which will allow everyone the time and opportunity to innovate, pilot, and invent in order to determine what does not work and what does. **EBDM**

Pharmacy Times
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Handelsman Traces Progress of Insulin Management

ANDREW SMITH

The specialized insulin formulations that keep emerging from pharmaceutical laboratories can control blood sugar far more effectively than the one-size-fits-all formulation of yesteryear. However, according to Yehuda Handelsman, MD, FACP, FACE, FNLA, patients and caregivers need to understand the ever-growing number of options.

Handelsman's presentation, "Insulin Management: Today and Tomorrow," part of, Patient-Centered Diabetes Care, explained what's available today, how doctors should deploy it, and what they should look for in years to come. The immediate past president of the American College of Endocrinology, Handelsman is the medical director and principal investigator of the Metabolic Institute of America. He also has a private practice in Tarzana, California.

Pharmaceutical insulin, he said, appeared as a treatment for diabetes in the 1920s. It was the first effective treatment for either type 1 diabetes (T1D) or advanced cases of type 2 diabetes (T2D), and many wrongly thought it would effectively cure the diseases.

Insulin still cannot control either disease perfectly, Handelsman said, but its efficacy has been greatly improved by 2 breakthroughs: the use of combination therapy and the ability to tweak the hormone's structure to change its speed of action. Today, he said, about 35% of all diabetics use insulin, with 20% of them using it in combination with some other medication and the rest using it as monotherapy. Most individuals with T1D use some form of the enzyme, as do many with advanced cases of T2D.

The American Diabetes Association (ADA) advises against using insulin, rather than an oral medication such as metformin, as an initial treatment for T2D. Some experts (although not the ADA guidelines) would also recommend against using insulin as the second or even the third drug in combination therapy, but exogenous insulin is unavoidable for patients with T2D who live long enough to lose the ability to produce their own insulin.

"Typically, we start with lifestyle management of people with diabetes. We move to a combination of oral medication, and then we go to basal insulin. From the algorithm that the [American Association of Clinical Endocrinologists] has done, what you can see here [is] that we kind of teach how to give the insulin. We can give it based on the level of A1C [glycated hemoglobin], or we can go by weight, or we can just start 10 units and see what happens," Handelsman said.

A couple of decades ago, the standard practice was to discontinue oral therapy once patients began using insulin. Research has since shown that adding basal insulin—that is, long-acting insulin—to the oral therapy controls A1C far better than insulin alone.

Choosing the right basal insulin can be tricky, however. Handelsman noted that some long-acting insulin formulations act longer than others and some may be less likely than others to produce hypoglycemia.

"The insulin degludec that I mentioned…it's a little bit different type of insulin than what we knew," Handelsman said. "This is an insulin that has a 25-hour half-life, so it has a 40-hour life. It's not good to give it every 2 or 3 days; it's good to give it every day. It reaches [maximum concentration] by about 4 days, and then there is no stacking. So, as we give the new dose, there is a breakdown of the previous dose and the patient stays there, stable. That actually allows us to give that insulin at any time."

Doctors can keep increasing the dose of basal insulin until it reaches 0.5 units/kg. Once a patient's condition deteriorates enough to render that dose insufficient, however, further increases are ineffective. Doctors should instead prescribe a fast-acting insulin to take around meal times. This second type of insulin increases both the complexity and pain of treatment. It also tends to reduce patient compliance.

Handelsman had hoped the introduction of an inhalable fast-acting insulin, called Afrezza, would improve compliance and outcomes. Trial results show the medication to be faster-acting than any other current product and, quite possibly, less likely to produce hypoglycemia. That said, Handelsman believes that a poor initial marketing campaign will prevent Afrezza from having any real impact on patient care for the foreseeable future. As for treatment options that are currently under development, he is most optimistic about several artificial pancreas devices that are under development by several groups and thinks one of them may hit the market by next year. **EBDM**

Joslin's Mitri Reviews Options for Improving CV Outcomes in Diabetes

ANDREW SMITH

Cardiovascular disease is the single biggest cause of death for Americans with diabetes,[1,2] but according to Joanna Mitri, MD, MS, of Joslin Diabetes Center, researchers have yet to answer many fundamental questions that would reduce this risk.

Studies have demonstrated that a few individual medications can save lives, Mitri noted during her presentation, "Options and Opportunities to Reduce Cardiovascular Risk in Type 2 Diabetes," during the meeting, Patient-Centered Diabetes Care. The effects of lifestyle interventions and even glycated hemoglobin (A1C) reduction, on the other hand, remain unclear.

"We know lifestyle is the cornerstone of clinical care in diabetes, and it is the foundation for cardiovascular disease prevention," Mitri said—right before she noted the surprising findings of the largest-ever study of lifestyle intervention on the cardiovascular health of patients with diabetes.

The Look AHEAD[3] study randomized more than 5000 patients to education or lifestyle intervention, from 2001 to 2012. The interventions were intense and, in many respects, successful.

"This lifestyle intervention gave the participants a tremendous amount of benefit," Mitri said. "There was weight loss. There was decrease in waist circumference. There were improvements in obstructive sleep apnea. There were decreases in urine infection, decreases in joint pain, and decreases in all the intermediate outcomes, which were glucose control, blood pressure control, and cholesterol level. So we know it gives a lot of benefit. However, unfortunately, the primary outcome [a composite of cardiovascular outcomes] was negative."

Trial results have provided similarly ambiguous information about A1C control, Mitri said. Hyperglycemia is undoubtedly associated with large increases in cardiovascular risk. Individuals with very high A1C levels suffer worse cardiovascular outcomes than people with lower A1C levels. However, a number of landmark studies—ACCORD,[4] ADVANCE,[5] and, for the most part, UKPDS[6]—have found little evidence that reductions in a particular patient's A1C levels also reduce that patient's cardiovascular risk.

"The specific role of anti-hyperglycemic therapy remains poorly understood," said Mitri, who noted that studies have also struggled to find cardiovascular benefits from reducing the blood pressure of patients with diabetes below 140/90 mm Hg. Lower blood pressure does appear to reduce stroke risk, though. Fortunately, there are some strategies that doctors can take to protect diabetics from cardiovascular disease.

Study results do indicate that metformin can improve cardiovascular outcomes. (Even so, Mitri added, such outcomes have never been tracked in a study that compared metformin with placebo,

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so the benefits are not certain.) Research has provided more concrete evidence to support the use of aspirin as a secondary therapy and to support the use of statins in patients with high cholesterol.

"I think it's very well established that aspirin does decrease your cardiovascular disease as a secondary prevention. In terms of primary prevention, you need to weigh the risk versus the benefit," she said. "Most lipid guidelines indicate that statin works in primary and secondary prevention, regardless if you do or don't have diabetes."

A number of medications approved in recent years to control blood sugar have undergone postmarketing testing to determine their effects on cardiovascular outcomes. None of the trials published to date have shown any benefit, but a press release on liraglutide indicates that its trial results will be the first.[7] Results from the EMPAG-REG trial released in September 2015 found that empagliflozin produced a benefit for the end point of CV death; the overall composite for this therapy was significant, but results for nonfatal heart attacks and strokes were not.[8]

"The first data [on liraglutide] will be released during the [American Diabetes Association] meeting," Mitri said. "But they were able to claim even superiority [in a press release], which means they were able to claim a decreased cardiovascular outcome, and not only in total, but in each of the MACE [major adverse cardiac event] outcomes, which means cardiovascular events, stroke, and cardiovascular mortality. And we will wait to see the results."

For patients willing to undergo the most radical of treatments, research into various types of bariatric surgery has found cardiovascular benefit, although randomized trials have never been conducted. Patients need not go that far to protect themselves, however. Research shows that they can reduce cardiovascular risk by giving up cigarettes. There is also evidence that they can also protect themselves by adopting a Mediterranean diet and monitoring their weight on a daily basis.

Indeed, Mitri said, no one doubts the importance of a healthy lifestyle or A1C control. Studies that fail to find benefits to particular regimens for controlling A1C or living better do not discredit such efforts. They do, however, indicate that researchers have much to learn about how to use them most effectively to improve outcomes. **EBDM**

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Investing in Adherence Starts With Figuring Out What Works—if Anything

ANDREW SMITH

Research has given patients with diabetes the tools they need to live far healthier lives and spend far less on medical care. Unfortunately, no one has figured out how to make patients use those tools effectively.

A panel discussion on "Paying for Adherence: Measuring Short-Term vs Long-Term Return on Investment," part of Patient-Centered Diabetes Care, outlined what research and experience say about the medical and financial efficacy of various efforts to change patient behavior. The speakers voiced some hope that cheap and easy technology will soon provide patients with the timely and customized reminders they need to take better care of themselves. The speakers noted, however, that most interventions—even the really logical ones that seemed destined to save money by keeping patients healthier—have thus far failed to demonstrate affordable benefits, particularly when they are evaluated in the real world rather than carefully-controlled trials.

"There's just a gestalt that these programs calling people asking [them] to take their medicine [will] work. They don't. The last person who's been able to influence just about everyone's behavior here has been his or her mother. We don't have the ability to call patients and get them to take their drugs," said Scott Breidbart, MD, chief clinical officer at Emblem Health.

There is, of course, evidence that interventions can work when they make adherence less expensive or when they remind genuinely forgetful patients to follow treatment regimens. "But where the intervention is expected to change someone's lifestyle, to get someone to take injections where they don't want to take injections, to get someone to eat less or live a healthier lifestyle, or to get someone to exercise when the person prefers to sit on a couch, that's not something we [payers] can accomplish," Breidbart said.

Research does indicate that patients who receive advice from their doctors, rather than their insurers, are more likely to modify their lifestyles. But for most patients, the scope and duration of the changes tend to be limited. To make matters worse, studies that appear to test very similar interventions can produce very different results.

In an "intervention that targeted statins, when they decreased the co-pay or waived any payment for statins, patients were much more adherent," said Joanna Mitri, MD, a clinical investigator at Joslin Diabetes Center. However, a similar intervention that reduced costs for blood pressure medication did not lead to lower blood pressure for the patients, she said.

Mitri suggested that payers experiment with increased payments for physicians who take the time to provide patients with more lifestyle counseling. Breidbart countered that he'd hesitate to test such a nebulous intervention. Each doctor would provide different counseling.

"I can measure if a patient got a hemoglobin A1C [test]," he said. "I can't measure the counseling that went on. So that's the difficulty. I accept that it takes more time, but I'm not sure how I would institute a process to pay for it."

Measurable outcomes are likewise important to the evaluation of any effort to improve treatment adherence. It is difficult to see whether a given intervention changes what patients eat at home. It is somewhat easier—though by no means easy—to see if the intervention reduces their risk of heart attack. Advances in information technology might make such analysis easier to perform. They might also enable payers and physicians to target different interventions at patients with different individual characteristics.

"Most adherence solutions improve adherence by 5% to 7%. So anybody that looks at any intervention sees a trivial improvement. But the truth is that in any intervention, there is a population of people that responds exquisitely well to that intervention, and we actually haven't been able to unlock that combination lock where a set of interventions customized to the individual would work tremendously well," said S. Sethu K. Reddy, MD, a senior consultant at Joslin Diabetes Center.

The panelists also saw some hope that lower-tech solutions might provide significant benefits, simply by making treatment adherence easier for patients. Deneen Vojta, MD, executive vice president at UnitedHealth Group, pointed out that research from low-income and middle-income countries shows that treatment adherence increases significantly when pharmacies combine several medications into single "poly pills." One pill might combine 2 blood pressure drugs, a statin and an aspirin.

"If we actually had an approved cardiovascular poly pill in this country, we would have more risk reduction than we would get with the PCSK9s for under a dollar a day," she said. **EBDM**

Jardiance®
(empagliflozin) tablets
10 mg/25 mg

JARDIANCE is an SGLT2 inhibitor for the treatment of adults with type 2 diabetes, in addition to diet and exercise

- Significant A1C reduction
- Once-daily oral dosing in the morning
- Significant weight loss demonstrated as a secondary endpoint*

* JARDIANCE is not indicated for weight loss.

INDICATION AND LIMITATION OF USE

JARDIANCE is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

JARDIANCE should not be used in patients with a history of serious hypersensitivity to JARDIANCE or in patients with severe renal impairment, end-stage renal disease, or dialysis.

WARNINGS AND PRECAUTIONS

Hypotension

JARDIANCE causes intravascular volume contraction. Symptomatic hypotension may occur after initiating JARDIANCE particularly in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. Before initiating JARDIANCE, assess for volume contraction and correct volume status if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

Ketoacidosis

Postmarketing reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in patients with type 1 and type 2 diabetes mellitus receiving SGLT2 inhibitors, including JARDIANCE. Patients who present with symptoms of metabolic acidosis should be assessed for ketoacidosis, even if blood glucose levels are less than 250 mg/dL. If suspected, discontinue JARDIANCE, evaluate and treat promptly.

Before initiating JARDIANCE, consider patient risk factors for ketoacidosis including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. Patients on JARDIANCE may require monitoring and temporary discontinuation of therapy in clinical situations known to predispose to ketoacidosis.

Impairment in Renal Function

JARDIANCE increases serum creatinine and decreases eGFR. Renal function should be evaluated prior to initiating JARDIANCE and periodically thereafter. More frequent monitoring is recommended with eGFR below 60 mL/min/1.73 m^2. The risk of impaired renal function with JARDIANCE is increased in elderly patients and patients with moderate renal impairment. JARDIANCE should be discontinued in patients with a persistent eGFR less than 45 mL/min/1.73 m^2.

Urosepsis and Pyelonephritis

Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been identified in postmarketing reports in patients receiving SGLT2 inhibitors, including JARDIANCE. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate for signs and symptoms of urinary tract infections and treat promptly.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues

Insulin and insulin secretagogues are known to cause hypoglycemia. The use of JARDIANCE with these agents can increase the risk of hypoglycemia. A lower dose of insulin or the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with JARDIANCE.

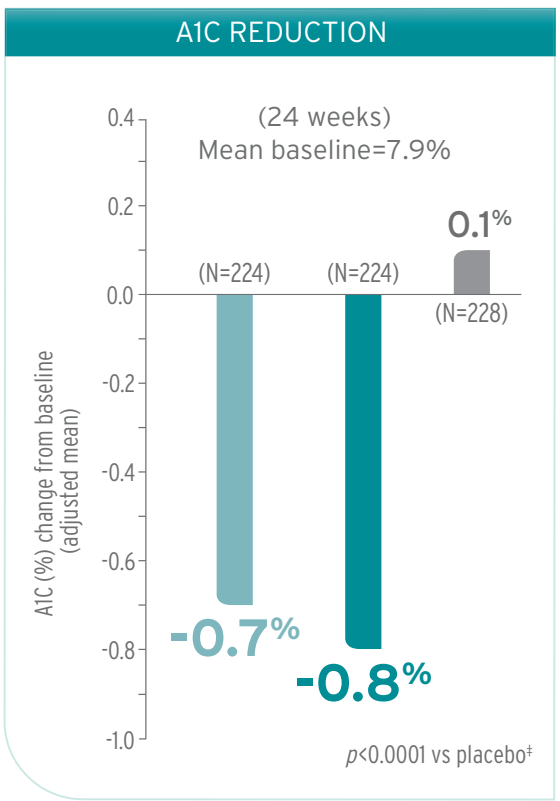
Genital Mycotic Infections

JARDIANCE increases the risk for genital mycotic infections. Patients with a history of chronic or recurrent genital mycotic infections were more likely to develop these infections. Monitor and treat as appropriate.

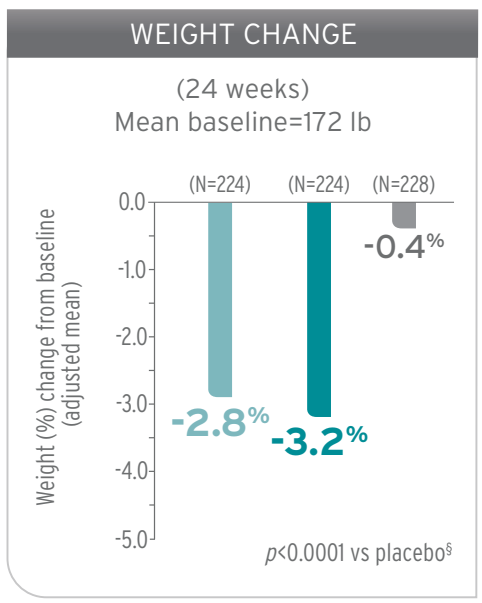
JARDIANCE is proven to significantly reduce A1C

In addition to lowering A1C, JARDIANCE significantly reduced weight†

JARDIANCE monotherapy vs placebo (24 weeks)



†JARDIANCE is not indicated for weight loss. Change from baseline in body weight was a secondary endpoint.[1]



‡A1C reduction: Difference from placebo (adjusted mean) was -0.7% and -0.9% for JARDIANCE 10 mg and 25 mg, respectively.

§Weight change: Difference from placebo (adjusted mean) was -2.5% and -2.8% for JARDIANCE 10 mg and 25 mg, respectively.

Study design: In a 24-week, double-blind, placebo-controlled study of 676 patients with type 2 diabetes mellitus, the efficacy and safety of JARDIANCE 10 mg (N=224) and 25 mg (N=224) were evaluated vs placebo (N=228). The primary endpoint was A1C change from baseline.[1]

JARDIANCE 10 mg and 25 mg significantly reduced systolic blood pressure (SBP)‖ by -2.6 mm Hg (placebo-adjusted, p=0.0231) and -3.4 mm Hg (placebo-corrected, p=0.0028), respectively, at 24 weeks[¶¶]

‖JARDIANCE is not indicated as antihypertensive therapy. Change from baseline in SBP was a secondary endpoint.[1]

¶SBP mean baseline: 133.0 mm Hg, 129.9 mm Hg, and 130.0 mm Hg for JARDIANCE 10 mg, 25 mg, and placebo, respectively.[1]

■ JARDIANCE 10 mg ■ JARDIANCE 25 mg ■ Placebo

Reference: 1. Data on file. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT; 2014.

IMPORTANT SAFETY INFORMATION (continued)

Increased Low-Density Lipoprotein Cholesterol (LDL-C)
Increases in LDL-C can occur with JARDIANCE. Monitor and treat as appropriate.

Macrovascular Outcomes
There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with JARDIANCE or any other antidiabetic drug.

ADVERSE REACTIONS
The most common adverse reactions (>5%) associated with placebo and JARDIANCE 10 mg and 25 mg were urinary tract infections (7.6%, 9.3%, 7.6%, respectively) and female genital mycotic infections (1.5%, 5.4%, 6.4%, respectively).

When JARDIANCE was administered with insulin or sulfonylurea, the incidence of hypoglycemic events was increased.

DRUG INTERACTIONS
Coadministration of JARDIANCE with diuretics resulted in increased urine volume and frequency of voids, which might enhance the potential for volume depletion.

USE IN SPECIAL POPULATIONS
Pregnancy
There are no adequate and well-controlled studies of JARDIANCE in pregnant women. JARDIANCE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers
It is not known if JARDIANCE is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from JARDIANCE, discontinue nursing or discontinue JARDIANCE.

Geriatric Use
JARDIANCE is expected to have diminished efficacy in elderly patients with renal impairment. The incidence of volume depletion-related adverse reactions and urinary tract infections increased in patients ≥75 years treated with JARDIANCE.

JAR PROF ISI 12.8.15

Please see Brief Summary of full Prescribing Information on the adjacent pages.

Boehringer Ingelheim

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(2/16) PC-JAR-0236-PROF

JARDIANCE® (empagliflozin) tablets, for oral use

℞ only

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Please see package insert for full Prescribing Information.

INDICATIONS AND USAGE: JARDIANCE is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitation of Use:** JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

CONTRAINDICATIONS: History of serious hypersensitivity reaction to JARDIANCE; Severe renal impairment, end-stage renal disease, or dialysis *[see Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS: Hypotension: JARDIANCE causes intravascular volume contraction. Symptomatic hypotension may occur after initiating JARDIANCE *[see Adverse Reactions]* particularly in patients with renal impairment, the elderly, in patients with low systolic blood pressure, and in patients on diuretics. Before initiating JARDIANCE, assess for volume contraction and correct volume status if indicated. Monitor for signs and symptoms of hypotension after initiating therapy and increase monitoring in clinical situations where volume contraction is expected *[see Use in Specific Populations]*. **Ketoacidosis:** Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization have been identified in postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose co-transporter-2 (SGLT2) inhibitors, including JARDIANCE. JARDIANCE is not indicated for the treatment of patients with type 1 diabetes mellitus *[see Indications and Usage]*. Patients treated with JARDIANCE who present with signs and symptoms consistent with severe metabolic acidosis should be assessed for ketoacidosis regardless of presenting blood glucose levels, as ketoacidosis associated with JARDIANCE may be present even if blood glucose levels are less than 250 mg/dL. If ketoacidosis is suspected, JARDIANCE should be discontinued, patient should be evaluated, and prompt treatment should be instituted. Treatment of ketoacidosis may require insulin, fluid and carbohydrate replacement. In many of the postmarketing reports, and particularly in patients with type 1 diabetes, the presence of ketoacidosis was not immediately recognized and institution of treatment was delayed because presenting blood glucose levels were below those typically expected for diabetic ketoacidosis (often less than 250 mg/dL). Signs and symptoms at presentation were consistent with dehydration and severe metabolic acidosis and included nausea, vomiting, abdominal pain, generalized malaise, and shortness of breath. In some but not all cases, factors predisposing to ketoacidosis such as insulin dose reduction, acute febrile illness, reduced caloric intake due to illness or surgery, pancreatic disorders suggesting insulin deficiency (e.g., type 1 diabetes, history of pancreatitis or pancreatic surgery), and alcohol abuse were identified. Before initiating JARDIANCE, consider factors in the patient history that may predispose to ketoacidosis including pancreatic insulin deficiency from any cause, caloric restriction, and alcohol abuse. In patients treated with JARDIANCE consider monitoring for ketoacidosis and temporarily discontinuing JARDIANCE in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery). **Impairment in Renal Function:** JARDIANCE increases serum creatinine and decreases eGFR *[see Adverse Reactions]*. The risk of impaired renal function with JARDIANCE is increased in elderly patients and patients with moderate renal impairment. More frequent monitoring of renal function is recommended in these patients *[see Use in Specific Populations]*. Renal function should be evaluated prior to initiating JARDIANCE and periodically thereafter. **Urosepsis and Pyelonephritis:** There have been postmarketing reports of serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization in patients receiving SGLT2 inhibitors, including JARDIANCE. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate patients for signs and symptoms of urinary tract infections and treat promptly, if indicated *[see Adverse Reactions]*. **Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. The risk of hypoglycemia is increased when JARDIANCE is used in combination with insulin secretagogues (e.g., sulfonylurea) or insulin *[see Adverse Reactions]*. Therefore, a lower dose of the insulin secretagogue or insulin may be required to reduce the risk of hypoglycemia when used in combination with JARDIANCE. **Genital Mycotic Infections:** JARDIANCE increases the risk for genital mycotic infections *[see Adverse Reactions]*. Patients with a history of chronic or recurrent genital mycotic infections were more likely to develop mycotic genital infections. Monitor and treat as appropriate. **Increased Low-Density Lipoprotein Cholesterol (LDL-C):** Increases in LDL-C can occur with JARDIANCE *[see Adverse Reactions]*. Monitor and treat as appropriate. **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with JARDIANCE or any other antidiabetic drug.

ADVERSE REACTIONS: The following important adverse reactions are described below and elsewhere in the labeling: Hypotension *[see Warnings and Precautions]*; Ketoacidosis *[see Warnings and Precautions)]*; Impairment in Renal Function *[see Warnings and Precautions]*; Urosepsis and Pyelonephritis *[see Warnings and Precautions)]* Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues *[see Warnings and Precautions]*; Genital Mycotic Infections *[see Warnings and Precautions]*; Increased Low-Density Lipoprotein Cholesterol (LDL-C) *[see Warnings and Precautions]*. **Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Pool of Placebo-Controlled Trials evaluating JARDIANCE 10 and 25 mg: The data in Table 1 are derived from a pool of four 24-week placebo-controlled trials and 18-week data from a placebo-controlled trial with insulin. JARDIANCE was used as monotherapy in one trial and as add-on therapy in four trials. These data reflect exposure of 1976 patients to JARDIANCE with a mean exposure duration of approximately 23 weeks. Patients received placebo (N=995), JARDIANCE 10 mg (N=999), or JARDIANCE 25 mg (N=977) once daily. The mean age of the population was 56 years and 3% were older than 75 years of age. More than half (55%) of the population was male; 46% were White, 50% were Asian, and 3% were Black or African American. At baseline, 57% of the population had diabetes more than 5 years and had a mean hemoglobin A1c (HbA1c) of 8%. Established microvascular complications of diabetes at baseline included diabetic nephropathy (7%), retinopathy (8%), or neuropathy (16%). Baseline renal function was normal or mildly impaired in 91% of patients and moderately impaired in 9% of patients (mean eGFR 86.8 mL/min/1.73 m^2). Table 1 shows common adverse reactions (excluding hypoglycemia) associated with the use of JARDIANCE. The adverse reactions were not present at baseline, occurred more commonly on JARDIANCE than on placebo and occurred in greater than or equal to 2% of patients treated with JARDIANCE 10 mg or JARDIANCE 25 mg.

Table 1: Adverse Reactions Reported in ≥2% of Patients Treated with JARDIANCE and Greater than Placebo in Pooled Placebo-Controlled Clinical Studies of JARDIANCE Monotherapy or Combination Therapy

	Number (%) of Patients		
	Placebo N=995	JARDIANCE 10 mg N=999	JARDIANCE 25 mg N=977
Urinary tract infection[a]	7.6%	9.3%	7.6%
Female genital mycotic infections[b]	1.5%	5.4%	6.4%
Upper respiratory tract infection	3.8%	3.1%	4.0%
Increased urination[c]	1.0%	3.4%	3.2%
Dyslipidemia	3.4%	3.9%	2.9%
Arthralgia	2.2%	2.4%	2.3%
Male genital mycotic infections[d]	0.4%	3.1%	1.6%
Nausea	1.4%	2.3%	1.1%

[a]Predefined adverse event grouping, including, but not limited to, urinary tract infection, asymptomatic bacteriuria, cystitis

[b]Female genital mycotic infections include the following adverse reactions: vulvovaginal mycotic infection, vaginal infection, vulvitis, vulvovaginal candidiasis, genital infection, genital candidiasis, genital infection fungal, genitourinary tract infection, vulvovaginitis, cervicitis, urogenital infection fungal, vaginitis bacterial. Percentages calculated with the number of female subjects in each group as denominator: placebo (N=481), JARDIANCE 10 mg (N=443), JARDIANCE 25 mg (N=420).

[c]Predefined adverse event grouping, including, but not limited to, polyuria, pollakiuria, and nocturia

[d]Male genital mycotic infections include the following adverse reactions: balanoposthitis, balanitis, genital infections fungal, genitourinary tract infection, balanitis candida, scrotal abscess, penile infection. Percentages calculated with the number of male subjects in each group as denominator: placebo (N=514), JARDIANCE 10 mg (N=556), JARDIANCE 25 mg (N=557).

Thirst (including polydipsia) was reported in 0%, 1.7%, and 1.5% for placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg, respectively. *Volume Depletion:* JARDIANCE causes an osmotic diuresis, which may lead to intravascular volume contraction and adverse reactions related to volume depletion. In the pool of five placebo-controlled clinical trials, adverse reactions related to volume depletion (e.g., blood pressure (ambulatory) decreased, blood pressure systolic decreased, dehydration, hypotension, hypovolemia, orthostatic hypotension, and syncope) were reported by 0.3%, 0.5%, and 0.3% of patients treated with placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg respectively. JARDIANCE may increase the risk of hypotension in patients at risk for volume contraction *[see Warnings and Precautions and Use in Specific Populations]*. *Increased Urination:* In the pool five placebo-controlled clinical trials, adverse reactions of increased urination (e.g., polyuria, pollakiuria, and nocturia) occurred more frequently on JARDIANCE than on placebo (see Table 1). Specifically, nocturia was reported by 0.4%, 0.3%, and 0.8% of patients treated with placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg, respectively. *Impairment in Renal Function:* Use of JARDIANCE was associated with increases in serum creatinine and decreases in eGFR (see Table 2). Patients with moderate renal impairment at baseline had larger mean changes. *[see Warnings and Precautions and Use in Specific Populations]*.

Table 2: Changes from Baseline in Serum Creatinine and eGFR in the Pool of Four 24-week Placebo-Controlled Studies and Renal Impairment Study

		Pool of 24-Week Placebo-Controlled Studies		
		Placebo	JARDIANCE 10 mg	JARDIANCE 25 mg
Baseline Mean	N	825	830	822
	Creatinine (mg/dL)	0.84	0.85	0.85
	eGFR (mL/min/1.73 m^2)	87.3	87.1	87.8
Week 12 Change	N	771	797	783
	Creatinine (mg/dL)	0.00	0.02	0.01
	eGFR (mL/min/1.73 m^2)	-0.3	-1.3	-1.4
Week 24 Change	N	708	769	754
	Creatinine (mg/dL)	0.00	0.01	0.01
	eGFR (mL/min/1.73 m^2)	-0.3	-0.6	-1.4
		Moderate Renal Impairment[a]		
		Placebo		JARDIANCE 25 mg
Baseline	N	187	–	187
	Creatinine (mg/dL)	1.49	–	1.46
	eGFR (mL/min/1.73 m^2)	44.3	–	45.4

Table 2 (Cont'd)		Placebo		JARDIANCE 25 mg
Week 12 Change	N	176	–	179
	Creatinine (mg/dL)	0.01	–	0.12
	eGFR (mL/min/1.73 m^2)	0.1	–	-3.8
Week 24 Change	N	170	–	171
	Creatinine (mg/dL)	0.01	–	0.10
	eGFR (mL/min/1.73 m^2)	0.2	–	-3.2
Week 52 Change	N	164	–	162
	Creatinine (mg/dL)	0.02	–	0.11
	eGFR (mL/min/1.73 m^2)	-0.3	–	-2.8

[a]Subset of patients from renal impairment study with eGFR 30 to less than 60 mL/min/1.73 m^2

Hypoglycemia: The incidence of hypoglycemia by study is shown in Table 3. The incidence of hypoglycemia increased when JARDIANCE was administered with insulin or sulfonylurea *[see Warnings and Precautions]*.

Table 3: Incidence of Overall[a] and Severe[b] Hypoglycemic Events in Placebo-Controlled Clinical Studies

Monotherapy (24 weeks)	**Placebo (n=229)**	**JARDIANCE 10 mg (n=224)**	**JARDIANCE 25 mg (n=223)**
Overall (%)	0.4%	0.4%	0.4%
Severe (%)	0%	0%	0%
In Combination with Metformin (24 weeks)	**Placebo + Metformin (n=206)**	**JARDIANCE 10 mg + Metformin (n=217)**	**JARDIANCE 25 mg + Metformin (n=214)**
Overall (%)	0.5%	1.8%	1.4%
Severe (%)	0%	0%	0%
In Combination with Metformin + Sulfonylurea (24 weeks)	**Placebo (n=225)**	**JARDIANCE 10 mg + Metformin + Sulfonylurea (n=224)**	**JARDIANCE 25 mg + Metformin + Sulfonylurea (n=217)**
Overall (%)	8.4%	16.1%	11.5%
Severe (%)	0%	0%	0%
In Combination with Pioglitazone +/- Metformin (24 weeks)	**Placebo (n=165)**	**JARDIANCE 10 mg + Pioglitazone +/- Metformin (n=165)**	**JARDIANCE 25 mg + Pioglitazone +/- Metformin (n=168)**
Overall (%)	1.8%	1.2%	2.4%
Severe (%)	0%	0%	0%
In Combination with Basal Insulin (18 weeks[c])	**Placebo (n=170)**	**JARDIANCE 10 mg (n=169)**	**JARDIANCE 25 mg (n=155)**
Overall (%)	20.6%	19.5%	28.4%
Severe (%)	0%	0%	1.3%
In Combination with MDI Insulin +/-Metformin (18 weeks[c])	**Placebo (n=188)**	**JARDIANCE 10 mg (n=186)**	**JARDIANCE 25 mg (n=189)**
Overall (%)	37.2%	39.8%	41.3%
Severe (%)	0.5%	0.5%	0.5%

[a]Overall hypoglycemic events: plasma or capillary glucose of less than or equal to 70 mg/dL
[b]Severe hypoglycemic events: requiring assistance regardless of blood glucose
[c]Insulin dose could not be adjusted during the initial 18 week treatment period

Genital Mycotic Infections: In the pool five placebo-controlled clinical trials, the incidence of genital mycotic infections (e.g., vaginal mycotic infection, vaginal infection, genital infection fungal, vulvovaginal candidiasis, and vulvitis) was increased in patients treated with JARDIANCE compared to placebo, occurring in 0.9%, 4.1%, and 3.7% of patients randomized to placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg, respectively. Discontinuation from study due to genital infection occurred in 0% of placebo-treated patients and 0.2% of patients treated with either JARDIANCE 10 or 25 mg. Genital mycotic infections occurred more frequently in female than male patients (see Table 1). Phimosis occurred more frequently in male patients treated with JARDIANCE 10 mg (less than 0.1%) and JARDIANCE 25 mg (0.1%) than placebo (0%). *Urinary Tract Infections:* In the pool five placebo-controlled clinical trials, the incidence of urinary tract infections (e.g., urinary tract infection, asymptomatic bacteriuria, and cystitis) was increased in patients treated with JARDIANCE compared to placebo (see Table 1). Patients with a history of chronic or recurrent urinary tract infections were more likely to experience a urinary tract infection. The rate of treatment discontinuation due to urinary tract infections was 0.1%, 0.2%, and 0.1% for placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg, respectively. Urinary tract infections occurred more frequently in female patients. The incidence of urinary tract infections in female patients randomized to placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg was 16.6%, 18.4%, and 17.0%, respectively. The incidence of urinary tract infections in male patients randomized to placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg was 3.2%, 3.6%, and 4.1%, respectively *[see Warnings and Precautions and Use in Specific Populations]*. *Laboratory Tests:* Increase in Low-Density Lipoprotein Cholesterol (LDL-C): Dose-related increases in low-density lipoprotein cholesterol (LDL-C) were observed in patients treated with JARDIANCE. LDL-C increased by 2.3%, 4.6%, and 6.5% in patients treated with placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg, respectively *[see Warnings and Precautions]*. The range of mean baseline LDL-C levels was 90.3 to 90.6 mg/dL across treatment groups. Increase in Hematocrit: In a pool of four placebo-controlled studies, median hematocrit decreased by 1.3% in placebo and increased by 2.8% in JARDIANCE 10 mg and 2.8% in JARDIANCE 25 mg treated patients. At the end of treatment, 0.6%, 2.7%, and 3.5% of patients with hematocrits initially within the reference range had values above the upper limit of the reference range with placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg, respectively. **Postmarketing Experience:** Additional adverse reactions have been identified during postapproval use of JARDIANCE. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure: Ketoacidosis *[see Warnings and Precautions]*; Urosepsis and pyelonephritis *[see Warnings and Precautions]*.

DRUG INTERACTIONS: Diuretics: Coadministration of empagliflozin with diuretics resulted in increased urine volume and frequency of voids, which might enhance the potential for volume depletion *[see Warnings and Precautions]*. **Insulin or Insulin Secretagogues:** Coadministration of empagliflozin with insulin or insulin secretagogues increases the risk for hypoglycemia *[see Warnings and Precautions]*. **Positive Urine Glucose Test:** Monitoring glycemic control with urine glucose tests is not recommended in patients taking SGLT2 inhibitors as SGLT2 inhibitors increase urinary glucose excretion and will lead to positive urine glucose tests. Use alternative methods to monitor glycemic control. **Interference with 1,5-anhydroglucitol (1,5-AG) Assay:** Monitoring glycemic control with 1,5-AG assay is not recommended as measurements of 1,5-AG are unreliable in assessing glycemic control in patients taking SGLT2 inhibitors. Use alternative methods to monitor glycemic control.

USE IN SPECIFIC POPULATIONS: Pregnancy: *Pregnancy Category C:* There are no adequate and well-controlled studies of JARDIANCE in pregnant women. JARDIANCE should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Based on results from animal studies, empagliflozin may affect renal development and maturation. In studies conducted in rats, empagliflozin crosses the placenta and reaches fetal tissues. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. **Nursing Mothers:** It is not known if JARDIANCE is excreted in human milk. Empagliflozin is secreted in the milk of lactating rats reaching levels up to 5 times higher than that in maternal plasma. Since human kidney maturation occurs *in utero* and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from JARDIANCE, a decision should be made whether to discontinue nursing or to discontinue JARDIANCE, taking into account the importance of the drug to the mother. **Pediatric Use:** The safety and effectiveness of JARDIANCE in pediatric patients under 18 years of age have not been established. **Geriatric Use:** No JARDIANCE dosage change is recommended based on age. A total of 2721 (32%) patients treated with empagliflozin were 65 years of age and older, and 491 (6%) were 75 years of age and older. JARDIANCE is expected to have diminished efficacy in elderly patients with renal impairment *[see Use in Specific Populations]*. The risk of volume depletion-related adverse reactions increased in patients who were 75 years of age and older to 2.1%, 2.3%, and 4.4% for placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg. The risk of urinary tract infections increased in patients who were 75 years of age and older to 10.5%, 15.7%, and 15.1% in patients randomized to placebo, JARDIANCE 10 mg, and JARDIANCE 25 mg, respectively *[see Warnings and Precautions and Adverse Reactions]*. **Renal Impairment:** The efficacy and safety of JARDIANCE were evaluated in a study of patients with mild and moderate renal impairment. In this study, 195 patients exposed to JARDIANCE had an eGFR between 60 and 90 mL/min/1.73 m^2, 91 patients exposed to JARDIANCE had an eGFR between 45 and 60 mL/min/1.73 m^2 and 97 patients exposed to JARDIANCE had an eGFR between 30 and 45 mL/min/1.73 m^2. The glucose lowering benefit of JARDIANCE 25 mg decreased in patients with worsening renal function. The risks of renal impairment *[see Warnings and Precautions]*, volume depletion adverse reactions and urinary tract infection-related adverse reactions increased with worsening renal function. The efficacy and safety of JARDIANCE have not been established in patients with severe renal impairment, with ESRD, or receiving dialysis. JARDIANCE is not expected to be effective in these patient populations *[see Contraindications and Warnings and Precautions]*. **Hepatic Impairment:** JARDIANCE may be used in patients with hepatic impairment.

OVERDOSAGE: In the event of an overdose with JARDIANCE, contact the Poison Control Center. Employ the usual supportive measures (e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment) as dictated by the patient's clinical status. Removal of empagliflozin by hemodialysis has not been studied.

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Obesity May Be a "Disease," but Stigma Remains a Barrier to Care, Kyrillos Says

MARY CAFFREY

Only 5% of patients with obesity who lose weight keep it off. Coverage for obesity drugs is improving, but remains uncommon. Plus, only a tiny fraction of the candidates for bariatric surgery have the operation, in part because 70% of physicians won't give referrals.[1]

All this leaves 93% of those who live with obesity with unmet medical needs,[1] according to Janine V. Kyrillos, MD, FACP, ABOM, an obesity specialist at Thomas Jefferson University Hospital in Philadelphia. Kyrillos led off the April 8, 2016, session on the needs of those with obesity at Patient-Centered Diabetes Care, presented by *The American Journal of Managed Care* and Joslin Diabetes Center.

The stigma associated with obesity—the idea that patients "did this to themselves"—still pervades thinking among many physicians, insurers, and employers, Kyrillos said, despite the 2013 declaration by the American Medical Association (AMA) that obesity is a disease.[2] She shared a study that found healthcare providers ranked only below patients' own family members in being associated with obesity bias.[3]

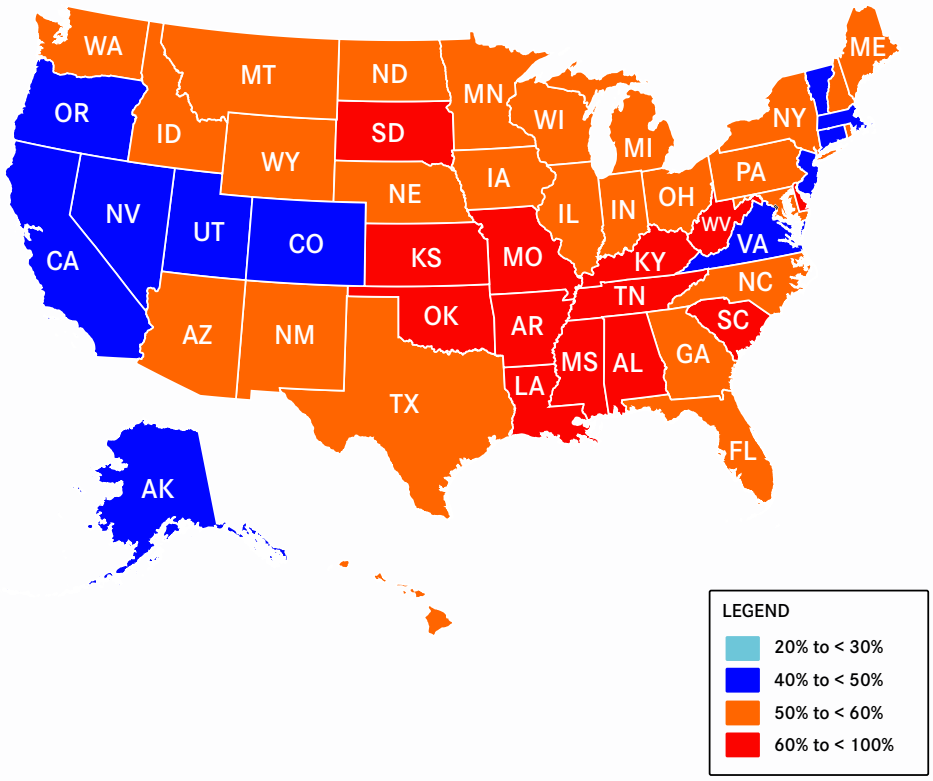
The AMA's declaration "has been met with a lot of controversy among providers," she said. There has been concern that patients will view managing obesity as futile, that it absolves them of responsibility. "But the real hope was also to [increase] research and bring more awareness to obesity. And I think that's happening very, very slowly—but it is happening."

As Kyrillos explained, the idea that patients can just be told "eat less, exercise more," fails to capture the many factors, including genetics and environmental causes, that have given rise to the epidemic. "Epigenetics is a newer field, which is so fascinating. What the mother does, and what the parents do, affect the gene expression of the children," which means if a woman is obese and gets pregnant, she is more likely to have a child who is overweight and diabetic than if she lost weight before becoming pregnant.

Even the basic understanding of the role and behavior of the adipocyte, or fat storage cells, has undergone a revolution, Kyrillos said. The same goes for the knowledge of the signals from the gut to the brain, and the interaction of key organs like the liver and pancreas in processing energy and producing insulin.[4] "There are over 100 different individual neurotransmitters and receptors in the gut that talk to the brain that control hunger and satiety," she said. They cannot all be turned off because humans are designed to see, eat, and store food. "If we knock out that instinct, the species would die, and we just have not evolved as fast as technology or the food supply," Kyrillos said.

Medicine had best take obesity treatment seriously, she said, and not only because it is linked to more than a dozen comorbid conditions. If current trends continue, states with the highest obesity rates today—in ranges above 35%—will reach 60% by 2030, Kyrillos said, showing a series of US maps that trace the march of the disease (FIGURE).[5]

FIGURE. Projected Obesity Rates by State, 2030[5]



Provider behavior, and especially bias toward patients who are not managing obesity, is a huge stumbling block, research finds. Harsh words directed at obese patients can cause 79% of them to simply eat more, and 75% will not try to diet at all.[3]

Kyrillos shared a powerful video that won an award from the American Society for Metabolic and Bariatric Surgery, featuring patients talking about taking responsibility for obesity while asking for an end to judgment and misunderstanding.[6] No one can assume an obese person overeats, doesn't exercise, or that their parents failed to raise them properly, as one young woman stated. One young man looked straight at the camera, and said:

You don't believe me.
You don't believe obesity is a disease.
You think I lack willpower.

Kyrillos said she knows many physicians have an outdated approach to obesity. "Many of my colleagues get frustrated. I know I do, in trying to get my patients to take personal responsibility," she said. "But I also get frustrated by the barriers to care, by the lack of coverage, the lack of resources. And I'm really hoping that more and more resources will go into figuring this out." **EBDM**

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Coverage for Obesity Improving, but More Progress Needed, Kyle Says

MARY CAFFREY

Payer coverage for obesity therapy and surgical treatment has improved recently, but more must be done—especially given the burden the disease presents, a leading advocate told attendees at Patient-Centered Diabetes Care (PCDC).

Ted Kyle, RPh, MBA, founder of ConscienHealth and chair of the Obesity Action Coalition, addressed attendees April 8, 2016, on the second day of the meeting presented by *The American Journal of Managed Care* and Joslin Diabetes Center. Too often, he said, healthcare discussions of obesity treat the disease as an abstraction instead of realizing that real people are living with this condition.

"Whether or not the healthcare plans cover care for obesity, we are paying for obesity," Kyle said. "Our sick care system does a great job of treating the result."

Untreated obesity harms nearly every organ system, he said, causing breathing problems, osteoarthritis, gout, cataracts, and liver and gallbladder issues. Obesity contributes to 2 of the costliest health conditions in the United States: diabetes costs $245 billion annually and heart disease costs $444 billion.[1,2]

The 2013 declaration by the American Medical Association that obesity is a disease was an important step—given that years ago, it would have been considered fraud to bill for obesity. However, reimbursement for therapeutics and other components of care has taken time to evolve, Kyle said. Another key step came when the US Preventive Services Task Force called for plans to cover obesity screening and evidence-based behavioral health counseling, he said. But, "working that out on the ground has been rather tedious."

Today, he said, formularies with 74 million covered lives now pay for obesity medication, and Saxenda—the version of liraglutide indicated for obesity—was included in the CVS Health formulary in 2016. Overall, however, uptake has been slow. In the weeks after PCDC, the *Pink Sheet* reported the difficulties that pharmaceutical companies have had selling FDA-approved therapies, despite the fact that more than one-third of US adults (34.9%) were obese as of 2012.[3,4]

Kyle shared employer data that show that although most large employer plans cover bariatric surgery and have for years, less than 50% of the plans that cover fewer than 500 employees will cover it. Of the employer-based wellness programs that are based on body mass index (BMI), 90% will pay for patients to see a doctor, but only 60% will pay for a dietitian, which is slightly more than half.

"There have long been coverage exclusions for obesity," Kyle said. He described going through chart reviews with some health plans and seeing the alarming number of cases where obesity medication might have been indicated, but being told,that plans would simply continue to pay for the results of comorbidities—like diabetes and strokes.

The ongoing problem of bias—the belief that persons with obesity "did it to themselves"—prevents care from being as comprehensive as it could be, he said. Kyle reported that nearly three-quarters (74%) of physicians don't screen for BMI, and the session also reported that 70% of doctors won't give referrals for surgery. Despite this, he said, there's good news: several recent studies have shown that bariatric surgery not only treats obesity, but the procedure can also reverse type 2 diabetes in some patients, making it more cost-effective.[5,6]

And, finally, CMS is moving forward with paying for prevention. Like several speakers, Kyle noted the giant step taken in late March when HHS Secretary Sylvia Mathew Burwell announced Medicare will soon pay for the National Diabetes Prevention Program. This evidence-based lifestyle initiative was shown to save Medicare $2650 per patient after 15 months for those who completed the program.[7]

"Bad coverage habits are dying hard," Kyle said. "But they *are* dying." **EBDM**

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Physician, Employer Attitudes Must Change Alongside Better Obesity Coverage, Panel Says

MARY CAFFREY

Small gains in improving payer coverage for obesity care are worth noting, but the US healthcare system remains well behind where it should be in treating the 93 million people with the disease, according to experts who took part in the discussion, "Overcoming Barriers to Access," during the April 8, 2016, session of Patient-Centered Diabetes Care (PCDC).

The 2016 meeting marked the first time that PCDC, presented by *The American Journal of Managed Care* and Joslin Diabetes Center, devoted an entire session to issues with obesity care and coverage, and just having the discussion was noteworthy to Fatima Cody Stanford, MD, MPH, MPA, FTOS, of Massachusetts General Hospital, who offered the provider voice on the panel.

As obesity specialists learn more about the physiology and the neuroscience behind the disease, the next step is better training of physicians—whose judgments can set back patients.

"Whether or not young physicians that are coming out of training are familiar with dealing with patients with obesity, they may not necessarily know how to adequately address the issue, but at least they're recognizing it as an issue for the first time," she said.

Joining Stanford were obesity care advocate Ted Kyle, RPh, MBA, of ConscienHealth, and Anne Schmidt, MD, associate medical director for Blue Cross Blue Shield (BCBS) of Alabama, representing

the payer voice. Meeting chairman Robert A. Gabbay, MD, PhD, FACP, CMO of Joslin Diabetes Center, moderated the discussion.

Payer coverage for obesity pharmaceuticals has not been uniform or robust. Stanford and Kyle have noted that despite the movement toward increased cost-sharing by employers for staff who fail to meet certain health targets, some of these same employers will not pay for obesity therapy. While there has been some improvement, "Unfortunately, we still are quite far behind, and I don't think we can pat ourselves on the back just yet," Stanford said.

Children with obesity, in particular, have limited options; typically, payers will only cover counseling or surgery, she said. Schmidt said that the transition from fee-for-service to a value-based system will help promote coverage for obesity care, because it will make sense to pay for services with proven outcomes. Evidence from clinical trials is important, Schmidt said, because a key challenge is convincing major employers with self-funded plans that obesity care is worth it.

In Alabama, she said, BCBS is initiating a process measure, asking physicians to record the body mass index (BMI) for all adults. Since Kyle pointed out that only 74% of doctors do this nationally, this change by Alabama's largest payer—in a state with high obesity rates—could open many discussions about making changes. The challenge here is getting employers with self-funded plans to buy into a value-based concept that promotes payment for evidence-based therapy, Schmidt added.

As Gabbay said during the discussion, no one would deny treatment to a person with type 2 diabetes and say, "Now, go get those blood sugars lower."

Stanford said that payer coverage is not the only challenge—the way physicians are trained must change, because the bias they carry about obesity does great harm. When a patient with severe obesity comes for a first visit, she said, "I have to have a box of Kleenex."

A typical patient with a BMI of 40 or higher will have tried multiple diets, including fad programs seen on TV, she said, but "they cry because the doctor told them they just didn't try hard enough."

"If one adds up all the money spent on things that don't work," Gabbay said, "We'd probably have money for the things that do work." **EBDM**

TECHNOLOGY & INNOVATION

Understanding the Conditions When EHRs Work for Patients With Diabetes

MARY CAFFREY

Broader use of electronic health records (EHRs) is among the legacies of the Affordable Care Act (ACA). Yet studies on their clinical impact in diabetes care have produced mixed results. Ilana Graetz, PhD, an assistant professor at the University of Tennessee Health Sciences Center, is interested in why that happens—and designed a study, she said, to "understand the conditions necessary to really make the most out of electronic health records."

Graetz presented research that first appeared in *The American Journal of Managed Care*[1] to attendees at Patient-Centered Diabetes Care. Funded by the Agency for Healthcare Research and Quality, Graetz's study involved a research tool to understand how office dynamics affect acceptance—and success—of EHRs in primary care, where much of diabetes treatment occurs.

"There's been very little research that looked at how the organizational environment can change how EHRs get adopted and used, and what impact they have on outcomes," Graetz said. Her point, if understudied, is obvious: simply plunking expensive technology into the workflow does little if users are not ready to embrace it.

Her research has both quantitative and qualitative elements. When Graetz spoke with primary care physicians (PCPs) about their EHR experiences, she heard that the sheer quantity of information can undermine its purpose. "One physician that I talked to said that 'the quantity of unnecessary information adversely impacts the care quality because it's overwhelming.'" Another told her, "There's so much information and repetition in the system that it's easy to miss the important points."

TABLE. Adjusted Association Between EHR Use and A1C and LDL-C Values by Primary Care Team Cohesion Level

	Average Change in A1C (%)	95% CI	Average Change in LDL-C (mg/dL)	95% CI
Higher team cohesion: EHR vs no EHR	−0.11[a]	−0.12 to −0.09	−2.15[a]	−2.43 to −1.86
Lower team cohesion: EHR vs no EHR[b]	−0.08[a]	−0.10 to −0.07	−1.42[a]	−1.80 to −1.03
Difference in EHR association for higher vs lower team cohesion[c]	0.02[d]	0.01-0.03	0.73[a]	0.41-1.11

A1C indicates glycated hemoglobin; EHR, electronic health record; LDL-C, low-density lipoprotein cholesterol.
[a]P <.001.
[b]The EHR effect for teams with lower cohesion was calculated by adding the EHR effect estimate to the interaction of EHR and lower team cohesion.
[c]The interaction coefficient for EHR and lower cohesion represents the difference in the EHR association on clinical outcome between higher versus lower team cohesion.
[d]P <.01.
We used linear regression with fixed effects at the patient level, adjusted for calendar quarter, calendar year, and dummy variables to control for medical center fixed effects.

Graetz's evaluation of PCP team dynamics builds on earlier work, which found that just having an EHR in a practice increased the likelihood that persons with diabetes would get annual screenings for glycated hemoglobin (A1C) and low-density lipoprotein (LDL) cholesterol.[2] "If they did have a lab value that was above their target, they were more likely to get the appropriate treatment intensification," she said. "And they were more likely to have reductions in A1C and LDL values."

Examining data from Kaiser Permanente as it implemented its Epic system from 2005 to 2010, Graetz sent surveys to primary care teams to understand what set apart the primary care practices with the best clinical results with EHR. She received 780 responses, about 50% of those she sent.

Then, Graetz assigned scores for "team cohesion" among the respondents, using an instrument developed to measure team climate at the primary care level. She then matched those up against A1C and LDL cholesterol results from 2005 to 2009—involving some 80,000 patients, with about half the readings coming before EHR implementation and half afterward. Of the patients, 85% were over age 50 and most had comorbidities.

The data analysis showed that when patients saw primary care teams with high levels of cohesion, the use of EHRs was "associated with significantly greater improvements in A1C levels (0.11 percentage point decrease in A1C) compared with patients who saw teams with low cohesion (0.08 percentage point decrease)"[1] (see **TABLE**).

LDL cholesterol results were similar. "You can see that all patients received a significant improvement in their LDL values, but that patients that were cared for by teams with higher cohesion got a significantly greater reduction in their LDL," she said. Her data showed high-cohesion teams were associated with a 2.15 mg/dL decrease, while low-cohesion teams saw just 1.42 mg/dL.[1]

"Some implication of the study is that organizational context is definitely important for understanding the impact that EHRs can have on quality outcomes," Graetz said. "It might not be enough to just turn on the EHR system if you don't have the organizational support and environment to support that transition."

"In the future, research should continue to look into not just, 'Does EHR improve outcomes?' but 'What are the conditions necessary to make the most of this investment?'" **EBDM**

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Omada Health Exec Shares How to Bring Behavioral Health of Diabetes Prevention to the Masses

MARY CAFFREY

When HHS Secretary Sylvia Mathews Burwell announced March 23, 2016, that Medicare would soon pay for the National Diabetes Prevention Program (NDPP),[1] leaders from digital behavioral health company, Omada Health, were on hand to share the news.

It was a milestone long in the making—starting with the 2002 publication of the National Institutes of Health study on the effectiveness of the NDPP, which was shown to produce a 58% risk reduction for diabetes over 3 years.[2] It continued with the passage of the Affordable Care Act, which made diabetes prevention a priority, with guidance from the US Preventive Services Task Force,[3,4] and the creation of the Center for Medicare & Medicaid Innovation, which funded the pilot project that showed the NDPP could save Medicare $2650 per person over 15 months.[1]

However, reaching the 86 million Americans who have prediabetes, before some of them join the 29 million who have the disease,[5] will require moving beyond the face-to-face model first conceived. As Mike Payne, MBA, MSci, chief commercial officer and head of medical affairs at Omada Health, told the attendees at Patient-Centered Diabetes Care, only 1% of those who could benefit from the NDPP have gone through the program, despite its proven effectiveness. A technology-driven solution that removes barriers like transportation costs and scheduling problems was needed, Payne explained.

Payer coverage in Medicare for NDPP could grow that 1% very quickly. "The fact that CMS has taken this step is really encouraging," he said. Reaching the masses with technology, however, requires looking to the behavioral sciences for guidance, even inspiration. Behavioral health programs, Payne explained, teach and offer social support, but "Also, you let them make mistakes and support them with cognitive coping skills in the community."

Omada Health's product is not telemedicine in the classic sense, he said, explaining, "It is an immersive experience for the patient, bringing clinical psychology in a group-based setting to your pocket, your computer, to your home, wherever you are." He played videos showing the audience a sample of what the participant sees and feels—despite being online, the atmosphere seems intensely personal. A huge priority is placed on design, to create a user experience that promotes not only adherence and engagement, but also allows the participant to enjoy the ride.

So far, the results show the approach is working. Omada Health started in 2011 with a commitment to clinical investment and peer-reviewed research on par with a pharmaceutical company, Payne said, because its leaders believed that would ultimately be required. That wasn't easy, because traditional clinical guidelines are not created with digital delivery in mind.

Not only is the company producing studies with the Veterans' Administration showing the program's value, and a paper on its long-term economic impact, but today, Payne said, "We have the biggest behavioral science data set in the world. And we've got quantitative data like weight, activity, and food." Beyond that, he said, there is plenty of "unstructured data," the texts of online conservations that can be mined for insights on why some individuals stay on track and others don't.

Already, Payne said, Omada has been able to draw a sharp line between 2 types of mindsets: those who come to the program with a "growth mindset," which embraces change, see a 10% weight loss over 4 months; by contrast, those with the "fixed mindset" have limited success.

The next question, Payne said, is how to treat the "fixed mindset" group differently to produce better results? "That's what we're tackling how," he said. And when asked, Payne said, Omada Health is working on programs to treat those who already have type 2 diabetes.

Omada's approach addresses an issue that is coming up more and more in diabetes care—what happens to the patient between visits to the doctor or the diabetes educator matters just as much, if not more, than the face-to-face visit with the clinician. There's nothing wrong with in-person support, Payne said, but this approach by itself isn't practical to reach the multitudes at risk for diabetes. Digital behavioral health, by contrast, "is going to allow you to multiply your impact by millions." **EBDM**

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Telehealth in Diabetes Care: *Patient Acceptance Exceeds Reimbursement*

MARY CAFFREY

A telehealth initiative through the University of Mississippi Medical Center (UMMC) is boosting medication adherence among poor patients with diabetes and keeping them out of the emergency department (ED). Getting these results elsewhere might be difficult, however.

Besides its design, the Mississippi program has another advantage: a state law that requires telehealth reimbursement. According to panelists at Patient-Centered Diabetes Care, payer coverage for telehealth is at a crossroads: without evidence, it's hard to expand reimbursement; without payment, it's hard to gather data that confirm telehealth is ideal for that "in-between time" when the doctor is not present.

Teasarnee Davis, DNP, APRN-BC, lead nurse practitioner for the UMMC Center for Telehealth, explained that the results of a study nearing conclusion are showing 96% medication adherence thus far. About 180 participants from the Mississippi Delta—all of whom had at least 1 hospital admission related to diabetes—were given a preloaded tablet and peripherals, such as a glucometer.

Patients receive a daily health lesson at a time they choose, and nurses working remotely track their clinical signs and intervene immediately if blood sugar rises or the patient skips therapy. The early results are promising: when Davis said that there had been no ED readmissions for diabetes among the first 100 participants, the audience gasped.

Without telehealth, Davis said, there was no way to know, in real time, if patients stopped medication due to stomach discomfort. "If they don't have anyone to talk to, or they're not serious about taking it, they'll stop it and you won't know until they come back to the clinic," she said.

Davis said the daily contact, along with positive support—not criticism—if a patient strays off dietary requirements, are keys to success. If there's a grandmother whose blood sugar shot up to 300 because she ate her grandchild's birthday cake, nurses will not say, "Shame on you; you shouldn't eat that birthday cake," but rather, "This is how much birthday cake you should eat," she said. Teaching patients to build their diet around family celebrations is more realistic than telling them to never eat dessert. When UMMC publishes its results, it will help build the case for reimbursement, a step other panelists said would go a long way to making telehealth scalable.

Anne Schmidt, MD, associate medical director for Blue Cross Blue Shield of Alabama, said payers definitely need evidence to support telehealth—and it's covered in some circumstances in her state. Schmidt agreed that the opportunity for daily monitoring between physician visits, "when life happens," held great promise in diabetes care. Besides monitoring, technology offers the possibility of "a sea change in the way that we're providing education."

Unfortunately, Mississippi's parity law is more the exception than the norm. Kristen McGovern of Sirona Strategies, which represents the Alliance for Connected Care, said CMS and Medicare lag behind with treatment reimbursement. Speaking to the health systems representatives in attendance, McGovern said that the transition to value-based care models will mean "it's going to be increasingly important for you to know what's happening when (patients) leave your facility, because you're going to be accountable for their outcomes."

The bottom line, Schmidt said, is that a lot of what's been tried to rein in diabetes has not worked and it's time to try something new. "I think we need to listen to our patients more, because then when we talk about patient-centered medicine or patient-centered prevention, the first thing is, 'Ask what they need, and listen to the answers.'"

The exchange between McGovern and Schmidt revealed the quandary that telehealth faces. According to a survey by the Health Care Cost Institute, reimbursement remains especially low among Medicaid providers, where it arguably could make the greatest difference. However, 89% of patients who used it said it improved their health.[1]

Moderator David Brumley, MD, MBA, senior medical director at Tufts Health Plan, asked McGovern to address fears that telehealth will increase utilization. McGovern said a study commissioned by the Alliance found that 13% of patients who used telehealth might have done nothing if it had not been available. But actuaries found that figure would have to rise to 32.8% of telehealth users for utilization to reach a "tipping point" that has an adverse budget impact.[2]

"Please experiment with telehealth," McGovern said, encouraging health systems to share data because plans and policymakers want to see it. "We really need a body of evidence to show that this works."

Schmidt agreed. "The more data we have, the more evidence that we have of impact on outcomes—and we're seeing that, obviously—then the more we can shape policy to support that," she said. **EBDM**

TOP, Anne Schmidt, MD, associate medical director of Blue Cross Blue Shield of Alabama, represented the payer perspective in discussions on obesity and telehealth.

MIDDLE, Joslin Diabetes Center's Heather Zacker, senior director of Care Alliance, reminded participants that diabetes is a 24/7 disease, not something that happens "once every 3 months at the endocrinologist's office."

BOTTOM, Meeting Chair Robert A. Gabbay, MD, PhD, FACP, senior vice president and chief medical officer at Joslin, noted during the obesity panel discussion that physicians would not admonish a person with diabetes to get his blood pressure under control.

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Using Population Health Guidelines to Reduce CV Risk. View at **http://bit.ly/1WC7NmH**

Nuances of Payer Coverage, Challenges of Patient Adherence in Diabetes Care

PART 1. SEE PART 2 IN THE SEPTEMBER ISSUE OF *EVIDENCE-BASED DIABETES MANAGEMENT*

ANDREW SMITH

Trials have shown that intensive interventions can greatly improve outcomes for many patients with type 2 diabetes (T2D). However, in a world of finite resources, caregivers and payers have struggled to adopt such ambitious methods .

How can they do better? What affordable and achievable strategies might translate exciting discoveries into improved care? *The American Journal of Managed Care* gathered some of the nation's most respected researchers and clinicians to discuss such issues from the standpoint of both provider and payer. The panel discussion took place ahead of the annual meeting of Patient-Centered Diabetes Care on April 7, 2016, in Teaneck, New Jersey.

Taking part were panelists Zachary Bloomgarden, MD, professor at the Ichan School of Medicine at Mount Sinai; Michael Gardner, MD, medical director at the Cosmopolitan International Diabetes and Endocrinology Center at the University of Missouri; John A. Johnson, MD, MBA, senior medical director at WellCare Health Plans; and Robert A. Gabbay, MD, PhD, FACP, senior vice president and chief medical officer at Joslin Diabetes Center. Dennis P. Scanlon, PhD, professor of health policy and administration at Penn State University, served as moderator.

Their discussion came amid important clinical and reimbursement news. Physicians were still sorting through the implications of SPRINT (Systolic Blood Pressure Intervention Trial),[1] which, in late 2015, found that persons with high cardiovascular (CV) risk without diabetes benefited from a targeted systolic blood pressure of 120 mm Hg. Two diabetes medications, empagliflozin and liraglutide, had been shown to have CV benefits in separate trials.[2,3] In addition, just 2 weeks prior, HHS Secretary Sylvia Mathews Burwell announced plans for Medicare to start funding the Diabetes Prevention Program, to help prevent those with prediabetes from progressing to full-blown disease.[4]

The panelists began by acknowledging the size of the problem. The American Diabetes Association estimates that nearly 28 million Americans have T2D and another 90 million American adults have prediabetes.[5] This patient population, everyone agreed, is far too large for the nation's 5000 endocrinologists—so primary care physicians, who spend only a tiny fraction of their training on diabetes, will continue to treat the vast majority of T2D cases.

"The role of the endocrinologist now is to take the most severely affected patients, take the most complex patients, and to tune them up and return them to their primary care provider," said Gardner. "But we also need to be reaching out to the primary care providers and providing education on the fundamentals of diabetic care."

Gardner then discussed an outreach program that appears both effective and affordable: a weekly teleconference that allows primary care providers from anywhere in Missouri to call in with case-based questions for endocrinologists at the university. Each discussion helps an individual patient and educates all the doctors on the line about some facet of diabetes care. There is, of course, nearly unlimited information available to primary care physicians who wish to learn about T2D, but the panelists found it unrealistic to expect true expertise from people charged with treating dozens of conditions—particularly given the complexity of T2D, the tendency of studies to produce apparently contradictory results, and the need to treat different patients with different regimens.

"That's where professional societies and specialists have a role, to be able to sift through the data and interpret it," said Gabbay. "I think the other area where we can make more strides are decision-support tools for providers at the point-of-care that would say, 'Based on these characteristics, the patient you're seeing fits into a character that's very similar to the SPRINT study group[1] or another study group. And therefore, here's what would be recommended.' I think there's a little bit of that [now], and I think you're going to see a whole lot more of that in the near future."

The panelists had mixed feelings about the potential of payer programs that use billing data to question treatment plans that appear to deviate from standards of care or to warn physicians about medications that might not work for a particular patient. They agreed that payers have useful information that physicians often lack (like the knowledge that a patient is taking another medication that could interact with a prescribed treatment), but they also worried that physicians might object to payer "meddling" and questioned the sophistication of the systems that exist today.

"We have to make sure that those guidelines [that spur payer interventions] are not 18 years old," said Bloomgarden. "I'm still getting e-mails or letters from various pharmacy benefit managers saying, 'Here's a patient with diabetes who is not receiving an ACE [angiotensin-converting enzyme] inhibitor or an ARB [angiotensin receptor blocker]. Why not?' Of course they do not know that the patient has had hypercalcemia and was intolerant of those medicines or has low blood pressure. So we really need to somehow integrate the journal findings in the latest developments, in the latest understanding of professional societies, into what we provide to clinicians to help them manage their patients."

The ultimate goal, everyone agreed, is to provide highly customized care based upon the latest research findings. Rather than using guidelines that urge physicians to start nearly all

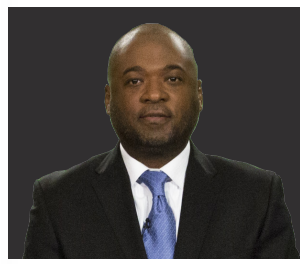
ABOUT THE PANEL

ZACHARY BLOOMGARDEN, MD

Dr Bloomgarden is professor at the Icahn School of Medicine at Mount Sinai, New York, NY.

DENNIS P. SCANLON, PHD

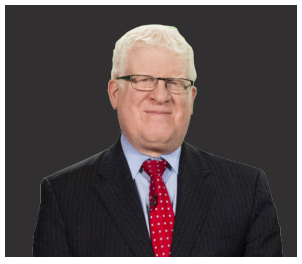
Dr Scanlon is professor of health policy and administration at Penn State University.



JOHN A. JOHNSON, MD, MBA

Dr Johnson is senior medical director at WellCare Health Plans.

ABOUT THE PANEL



ROBERT A. GABBAY, MD, PHD, FACP

Dr Gabbay is senior vice president and chief medical officer at Joslin Diabetes Center.

MICHAEL GARDNER, MD

Dr Gardner is medical director, Cosmpolitan International Diabetes and Endocrinology Center, University of Missouri.

patients on metformin and then choose randomly among dozens of second-line therapies, physicians would use algorithms that considered comorbidities and other patient characteristics to select the most appropriate treatment progressions for each individual.

"There actually has been a nice step forward in terms of the [treatment progression summaries] with ACE [American College of Endocrinology], in particular, showing these agents have these strengths, strength of effect, and also risk of side effect, and giving them some ranking. The previous guidelines have sort of been metformin and then anything else," said Gardner, who went on to discuss how individual patient concerns should influence treatment options. "Sometimes [it requires] sitting down and talking with that patient, [and asking,] 'Well why aren't you doing insulin? What are your concerns? What are your priorities? Is your priority to get your A1C [glycated hemoglobin] down? Or is your priority not to have these side effects, not to have hypoglycemia? Do you live alone? Do you have some cognitive challenges?' And trying to build a treatment program for them, which is really what patient-centered care is all about."

The panelists also debated the proper consideration of treatment costs. Gardner and Bloomgarden argued that some payers encouraged medically inferior treatments by refusing (at least initially) to pay for options that produced demonstrably superior outcomes. For example, Gardner said, head-to-head trials show that glucagon-like peptide-1 receptor agonists produce less weight gain and less hypoglycemia (and often better glycemic control) than insulin glargine; however, some payers won't cover the newer medications unless the insulin somehow fails to reduce blood sugar. Bloomgarden argued that such restrictions could actually increase long-run costs by creating inferior outcomes. That said, Gardner acknowledged that formulary controls were understandable (and probably necessary) given that pharmaceutical companies charge large premiums for new medications that are sometimes only modestly better than far cheaper generics.

Speaking for his own company, Johnson said that physicians and patients were often steered toward particular medications in each drug class—especially in Medicare and Medicaid—but that it was unusual for them to be steered toward particular classes. "At WellCare, we do make an attempt to make the most cost-effective agent in the different classes available to our members. And where there's justification to say there's an exclusion and you need to take an alternate path, with the documentation, we've had no issues with approving that," he said. "The important thing is the medications are tools, and when you're operating in the government-sponsored space, you want to make sure that you're stewards of the state and the federal government's money, and we're using that wisely to make available to our members the most cost-effective agents."

> **"If you look at all the evidence, there have been significant improvements in diabetes care by moving toward a patient-centered medical home model."**
>
> —MICHAEL GARDNER, MD

The panelists all acknowledged that few patients today receive individualized care based on the latest research. They also acknowledged that it would be a challenge getting primary care providers to deliver such care, even if guidelines made it relatively easy. Most primary practices today do not even reach out every 6 months to schedule appointments with patients whose A1C is over 9%, Gabbay said, even though such outreach is easy to do and research indicates that it significantly improves outcomes.

Indeed, although getting care providers to adopt best practices in a timely fashion is nearly as hard as getting patients to comply with treatment regimens, the panelists believe that the move to replace service-based payments with outcome-based payments will motivate providers to adhere closer to best practices. They also believe that efforts to pay for outcomes rather than inputs may help spur a transition from a model of diabetes care that relies mostly on physicians and prescription drugs to a model that also uses other care providers to improve patient lifestyles.

"If you look at all the evidence, there have been significant improvements in diabetes care by moving toward a patient-centered medical home model," Gardner said. "But that, in and of itself, is not the full answer because, again, only a portion of healthcare happens within that practice. And small practices may not have all of the different types of professionals that can help. So you mentioned diabetes educations and dieticians. The typical primary care practice isn't going to have that embedded in the practice, and that's where centers of excellence can, in diabetes, be able to send people, educators, dietitians, to various primary care practices once a week or whatever that model might look like."

Such visits from experts who could develop diet and exercise programs for patients could occur in person or online. Another model for practices that are too small to employ full-time nutritionists, counselors, and personal trainers might be to contract on a per-patient basis with independent local providers and use electronic health record systems to coordinate care. Physicians would use their outcome-based fees to pay the other service providers. In many cases, however, providers may have a simpler option: sending patients to use the support services offered by the payers who run their health plans.

"On the managed care side, in the government-sponsored space, we offer case and disease management programs that are interdisciplinary teams that partner with the provider," Johnson said. "For example, we may have a pharmacist, a nurse, a social worker, and a community health worker who help us locate our members in the community who have diabetes and connect them to those resources. So that is a benefit that we offer our most vulnerable at-risk members. In the commercial space, it's generally offered to the employers as an add-on benefit."

Using such programs on the worst-off patients, the panelists agreed, would ideally be a stepping stone toward using them on all willing patients who have T2D and then on willing members of the much larger patient population with prediabetes. But the path toward such care will not be an easy one.

"The dilemma is that we've all known for decades that physical activity and healthy diet will prevent the development of diabetes, and the Diabetes Prevention Program that Michael mentioned, the [Diabetes Prevention Program] absolutely showed that actually it's better than medication in preventing the development of diabetes," Bloomgarden said. "But delivering that intervention is tremendously difficult, and it requires a high level of interaction between healthcare providers, not necessarily tremendously trained, but individuals who will encourage people to eat right and exercise right. And getting that daily exercise; walking the 10,000 steps; limiting your diet, is just very hard for many people to do." **EBDM**

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Real-World Evidence on Canagliflozin:
A1C Declines, Some Patients Can Replace Other Drugs

MARY CAFFREY

This session was sponsored by Janssen Pharmaceuticals.

The SGLT2 inhibitor canagliflozin, sold as Invokana by Janssen Pharmaceuticals, has produced significant real-world declines in glycated hemoglobin (A1C) for patients with type 2 diabetes (T2D), with some patients able to stop taking other drugs, according to a presentation by Silvio Quaglia, MD, a Millburn, New Jersey-based physician who is board-certified in internal medicine. Quaglia was the luncheon speaker at Patient-Centered Diabetes Care, presented by The American Journal of Managed Care and Joslin Diabetes Center on April 8, 2016.

Canagliflozin was the first of the sodium-glucose co-transporter-2 (SGLT2) inhibitors to gain FDA approval in 2013,[1] and more than 7 million prescriptions have been sold, according to Quaglia. According to Janssen data, canagliflozin is used both as a monotherapy (19%) and as part of multi-drug regimens, including 26% of patients who have used it alongside insulin.

Canagliflozin and other drugs in the SGLT2 inhibitor class have a unique mechanism of action that allows the therapy to function separately from the rest of a T2D regimen. Normally, the SGLT2 protein operates in the proximal convoluted tubule of the kidneys and controls 90% of glucose reabsorption, after filtration. Canagliflozin and others in the SGLT2 inhibitor class block this protein, allowing excess glucose to be expelled in the urine and for the body to use remaining glucose more efficiently. Patients taking canagliflozin can lose weight and increase insulin sensitivity.

Thus, besides improving glycemic control, canagliflozin can allow patients to eliminate other drugs from their T2D regimen, especially diuretics. Canagliflozin is available in 100-mg and 300-mg doses; the lower dose is recommended for all patients starting therapy.

SGLT2 inhibitors now appear in guidelines from the American Association of Clinical Endocrinologists/American College of Endocrinology, Quaglia said, and this class is now the leading oral therapy option after metformin. SGLT2 inhibitors can be used as monotherapy, although they are more typically prescribed as an add-on therapy after metformin or perhaps a drug combination. (Glugacon-like peptide-1 [GLP-1] receptor agonists are also highly recommended, but this class is available only by injection.[2])

Quaglia reviewed both clinical trials, the results of which show canagliflozin outperforms another popular T2D medication, and real-world evidence, which shows the therapy is helping patients achieve A1C results seen in trials—while allowing some of them to stop taking other drugs.

CANAGLIFLOZIN VS SITAGLIPTIN

Quaglia presented results of a 2013 study by Schernthaler et al in *Diabetes Care*[3] comparing 377 patients taking 300 mg of canagliflozin with 100 mg of sitagliptin. Both groups were taking metformin and sulfonylurea background therapy and had a baseline A1C of 8.1%. The group taking 300 mg of canagliflozin experienced an average 1.03% drop in A1C compared with an average of 0.66% for sitagliptin. Nearly half (47.6%) of the canagliflozin group achieved an

ABOUT THE EXPERT

SILVIO QUAGLIA, MD

Dr Quaglia is board-certified in internal medicine. His practice, Associates in Primary Care, PA, is located in Millburn, NJ. He is a consultant for Janssen Pharmaceuticals.

FIGURE. Sodium-Glucose Co-transporters and Normal Renal Handling of Glucose[1]

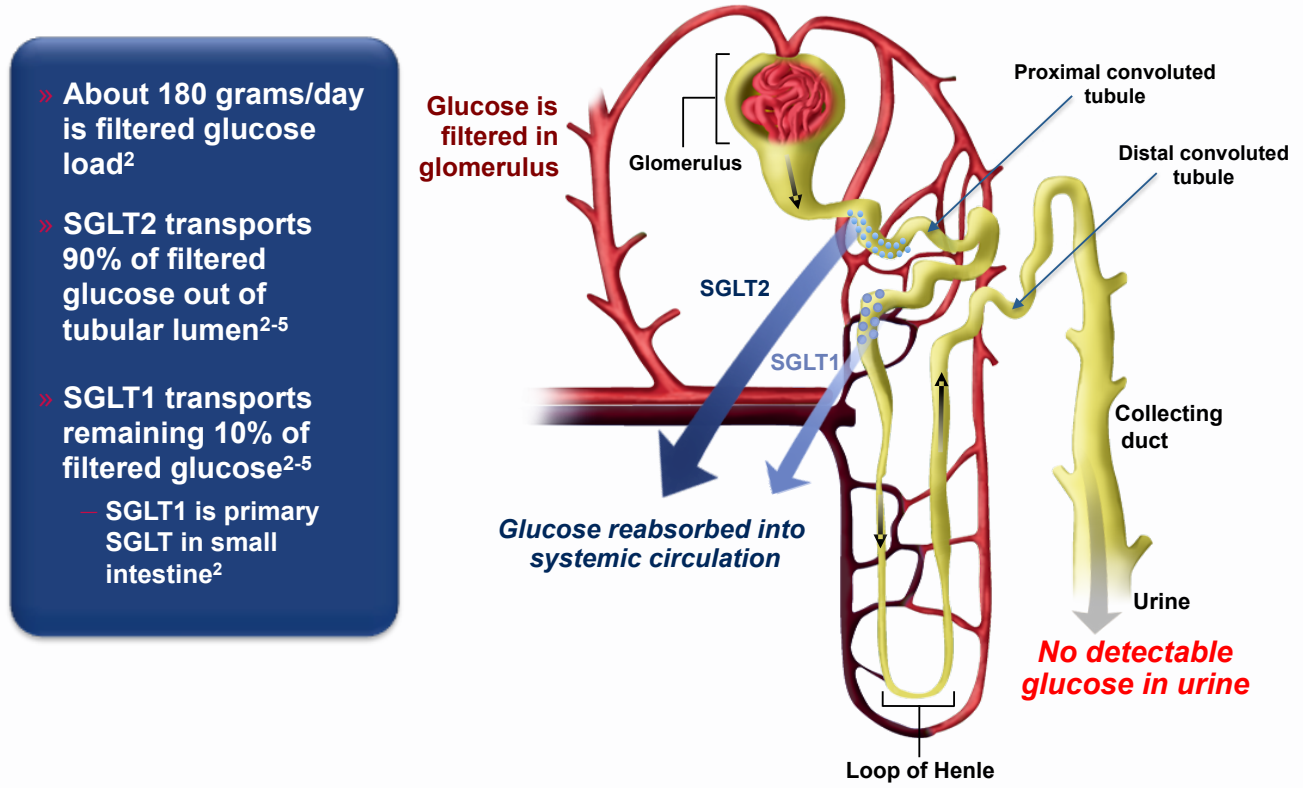

Figure adapted with permission from Bays H.
SGLT = sodium-glucose co-transporter.
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> Canagliflozin and other drugs in the SGLT2 inhibitor class have a unique mechanism of action that allows the therapy to function separately from the rest of the T2D regimen.

The potential for canagliflozin to allow some patients to stop taking another therapy is notable in light of recent position statements from ADA and EASD.

A1C goal of 7%, while only 35.3% of those taking sitagliptin achieved this goal.[3]

Although not prescribed for weight loss, canagliflozin produced more weight loss in the study than sitagliptin. After a year, patients taking canagliflozin had an average weight loss of 2.5%, or 5.1 pounds, while those taking sitagliptin lost 0.3% of their weight, or 0.2 pounds.

REAL-WORLD RESULTS

Real-world patients who took canagliflozin have had results consistent with clinical trials, Quaglia said. In December 2015, a claims analysis of 4017 patients who took canagliflozin appeared in *BMC Endocrine Disorders*.[4] As was the case in the study by Schernthaner, those who started with the highest A1C levels showed the most dramatic results.

Among 826 patients with a mean baseline A1C of 8.59%, there was an average drop in A1C of 0.81%. Of these, 715 patients who started the study with an A1C of at least 7.0% (mean 8.92%) fell 0.97%. Of these, 501 patients started with a mean A1C of at least 8.0% (average 9.54%) and had a drop of 1.3%. And in the group of 270 patients who started with an A1C of at least 9.0% (average 10.51%), the mean drop in A1C was 1.81%.[4]

This same study also examined whether patients who started canagliflozin were able to discontinue other diabetes medications.[3] The results were:

- Of the 2091 patients taking metformin, 235 stopped taking it, for an 11.0% reduction.
- Of the 1113 patients taking sulfonylureas, 140 stopped therapy, for a 12.6% reduction.
- Of the 934 patients taking a dipeptidyl peptidase-4 inhibitor, 139 stopped therapy, for a 14.9% reduction.
- Of the 786 patients using basal insulin, 121 stopped, for a 15.4% reduction.
- Of the 654 patients using GLP-1 receptor agonists, 107 stopped, for a 16.4% reduction.
- Of the 372 patients taking thiazolidinediones (TZDs), 41 stopped taking them, for an 11% reduction.
- Of the 344 patients using bolus insulin, 73 stopped using it, for a 21.2% reduction.
- Of 96 patients using pre-mixed insulin, 13 stopped, for a 13.5% reduction.

The potential for canagliflozin to allow some patients to stop taking another therapy is notable in light of the position statement from the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD). Quaglia presented the ADA/EASD matrix for adding second- or third-line therapy, which notes that the SGLT2 inhibitor class presents a low risk of hypoglycemia relative to basal insulin, with opportunity for weight loss and relatively few side effects (dehydration and genitourinary infections). Older classes of therapy, such as TZDs and sulfonylureas, are associated with weight gain and more serious side effects.[5] **EBDM**

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FDA Finalizes Nutrition Labels That Highlight Added Sugar

MARY CAFFREY

An updated Nutrition Facts Label will be find its way onto food packaging by 2018, now that the FDA has finally approved an overhaul to the 20-year-old design.[1]

The new label, based on evidence that informed both the 2010 and 2015 updates to the *Dietary Guidelines for Americans*, requires food manufacturers to highlight added sugars and base calorie counts on more realistic serving sizes.[2] Although the FDA says the "iconic" look remains, the label features a major design change: much larger type for the overall calorie count per serving. The FDA announced the changes May 20, 2016, nearly a year after the "Added Sugars" requirement was discussed and more than 2 years after initial changes to the label were proposed.[3]

For the Obama Administration, the food label represents a lasting reminder of First Lady Michelle Obama's efforts to promote healthy eating among children, amid high levels of backlash from industry and school nutrition leaders. Some groups feel the first lady's efforts have gone too far and created financial losses for suburban school districts, where children routinely threw out fruits and vegetables on their trays or declined to buy lunch at all.

"I am thrilled that the FDA has finalized a new and improved Nutrition Facts label that will be on food products nationwide," said Mrs. Obama in a statement from the FDA. "This is going to make a real difference in providing families across the country the information they need to make healthy choices."[4]

"For more than 20 years, Americans have relied on the Nutrition Facts label as a leading source of information regarding calories, fat, and other nutrients to help them understand more about the foods they eat in a day," said FDA Commissioner Robert Califf, MD, who is a cardiologist. "The updated label makes improvements to this valuable resource so consumers can make more informed food choices—one of the most important steps a person can take to reduce the risk of heart disease and obesity."[4]

Professional medical societies have placed more emphasis on nutrition and lifestyle choices at recent scientific meetings, now that the Affordable Care Act places a higher priority on preventive steps to reduce healthcare spending. At the most recent gathering of the American College of Cardiology (ACC), a half-day lifestyle intensive kicked off with Kim Allan Williams, MD, then the ACC president, discussing his decision to follow a vegan diet.[5]

The decision to require manufacturers to break out "Added Sugars" separately is rooted in studies that show it is difficult to consume recommended nutrients and stay within calorie goals if more than 10% of a day's calories come from added sugars. For most Americans, the percentage is closer to 13%, and nutrition advocacy groups have taken aim at sugar-sweetened beverages, especially soda, as the best way to cut out added sugar. The line for added sugars comes under the "Total Sugars" section of the label.

Percent Daily Value. Food components such as fat, nutrients, and carbohydrates will still be calculated as a percentage of the daily value of a typical diet, but the term is now defined on the label based on a 2000-calorie diet. The percentages will be updated to reflect new requirements for stating serving size.

Nutrients. Other significant changes to the Nutrition Facts Label include the addition of vitamin D and potassium, based on research that shows Americans often lack adequate levels of these nutrients in their diets. Vitamin D is important for bone health, and potassium helps control blood pressure. Calcium and iron will remain on the label as well. Vitamin A and C are being eliminated because deficiencies in these areas have become less common, although manufacturers are allowed to list these nutrients if they wish.

Listing Fat. The new label will continue to require listings for "Total Fat," "Saturated Fat," and "Trans Fat," but calories from fat will be eliminated, because new research shows the type of fat is more important than the amount.

Most food manufacturers have until July 26, 2018, to make all changes, but smaller products (with less than $10 million in annual sales) will have an extra year. Foods imported to the United States must meet labeling requirements. **EBDM**

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FDA Proposes Lower Sodium Levels for Processed Foods

MARY CAFFREY

Restaurants and food manufacturers would be asked to gradually lower the amount of sodium in processed and commercially prepared food, under the federal government's first-ever attempt to get Americans to eat less salt.

The FDA issued a draft guidance June 1, 2016, for short-term (2 years) and long-term (10 years) voluntary targets for the food industry, with the hope of bringing the current daily average intake of 3400 mg down to the recommended level of 2300 mg. High sodium consumption is blamed for the fact that 1 in 3 Americans has high blood pressure, a risk factor for heart attacks and strokes.[1] CDC estimates these new sodium targets would save 500,000 lives of the next decade, as well as $100 billion in healthcare costs.

FDA Commissioner Robert Califf, who is a cardiologist, said that many people may not be conscious of how much sodium they are eating until they get sick. "Our great hope is that this will initiate a very serious national dialogue," he said.[2]

"Many Americans want to reduce sodium in their diets, but that's hard to do when much of it is in everyday products we buy in stores and restaurants," said HHS Secretary Sylvia Mathews Burwell in a statement. The announcement, she said, "is about putting power back in the hands of consumers so that they can better control how much salt is in the food they eat and improve their health."[2]

According to the statement, the FDA wants to zero in on the big sodium sources—the 10% of packaged foods that account for 80% of sales. With about half of food spending on items eaten outside the home, these sources can't be ignored. The proposed guidance covers nearly 150 product categories, from baked goods to soups.

The FDA's short-term target would get sodium levels down to 3000 mg a day, with the 10-year goal bringing intake in line with Institute of Medicine recommendations. The graduated target allows the food industry to slowly take sodium from products, which will cause less resistance from consumers. (Several big names in the industry, such as Mars and Nestle, have been cutting back sodium on their own.) The timeline also gives companies time to develop alternatives to salt for improving flavor. Food manufacturers have successfully used this strategy with popular products that contain high amounts of added sugar, as it became clear the FDA would do more to reduce sugar consumption.

The Center for Science in the Public Interest, a nutrition advocacy group that has supported sodium menu labels in New York City, said today's guidance responds to the group's lawsuit against the FDA to compel lower sodium limits. CSPI President Michael F. Jacobson said he was disappointed that the guidance is voluntary and that the FDA simultaneously denied CSPI's petition for mandatory limits.[3]

"We hope that the industry will work cooperatively with the FDA and health experts to achieve the proposed reductions, which would benefit the health of all Americans," Jacobson said. He said the guidance does provide goals to keep all companies accountable and helps "level the playing field" for those already voluntarily cutting out sodium.[3] **EBDM**

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