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**INNOVATIONS**  
IN DIABETES CARE

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## Moderator

**Nancy D'Hondt, RPh, CDE, FADE**  
Staff/Clinical Pharmacist and Diabetes Educator, St. John Providence Hospital and Medical Center  
President-elect of the American Association of Diabetes Educators



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## Speakers

**Daniel J. Kent B.S. PharmD CDE**  
Clinical Specialty Program Coordinator;  
Infectious Disease, Endocrinology, Pharm Admin,  
Group Health Cooperative



**Paula J. Eichenbrenner CAE**  
Executive Director, AMCP Foundation  
Academy of Managed Care Pharmacy (AMCP)




## AMCP Partnership Forum

- **Objective:** AMCP convened a Partnership Forum for stakeholders to focus on innovations in diabetes care that are producing changes to treatment options, patient engagement, accountability and patient-provider interactions.
- **Key Stakeholders:** Pharmaceutical industry, managed care industry, health care providers, pharmacoeconomic experts, health policy experts, and patient advocates.
- **Date:** July 19-20, 2016 in Washington, DC

**Process:**

- Participants examined how new therapies and tools — such as those administered in a physician’s office and those delivered by mobile Health (mHealth) solutions— are changing the delivery of care and improving patient outcomes.
- Participants identified gaps in evidence for adopting novel diabetes treatments and provided recommendations on clinical outcomes of importance to managed care organizations.

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- 29 million individuals with diabetes in the United States in 2015
- 7<sup>th</sup> leading cause of death
- Annual costs of \$245 billion
  - More than \$1,000 per person in the country
- Prevalence is increasing

American Diabetes Association. *Diabetes Care*. 2013;36:1033-46.  
<https://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf>.  
Dall TM et al. *Diabetes Care*. 2014;37:3172-9.

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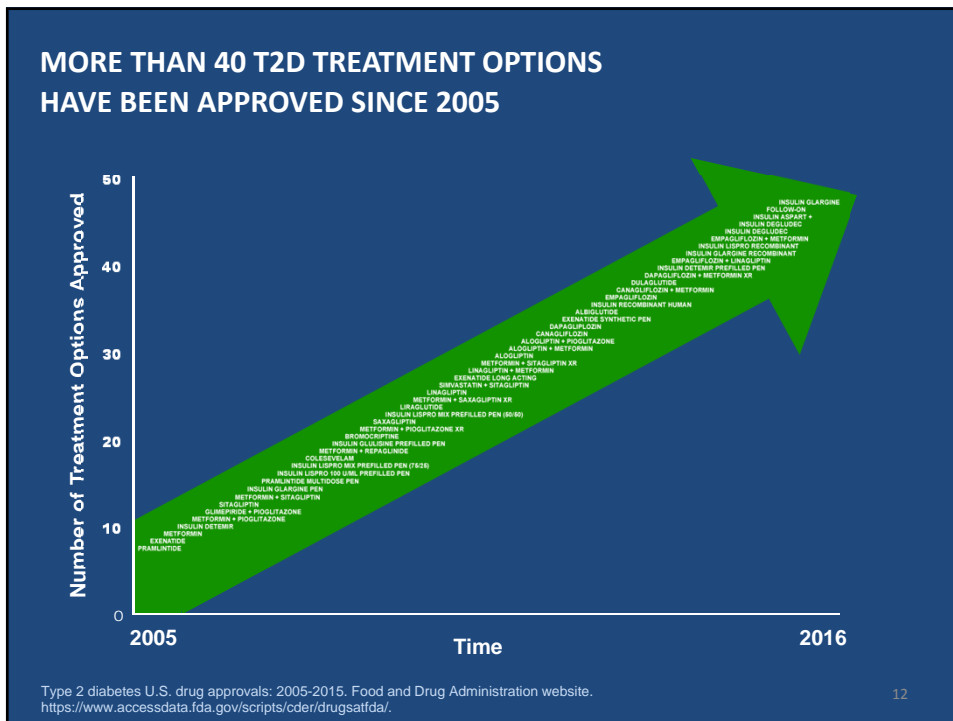
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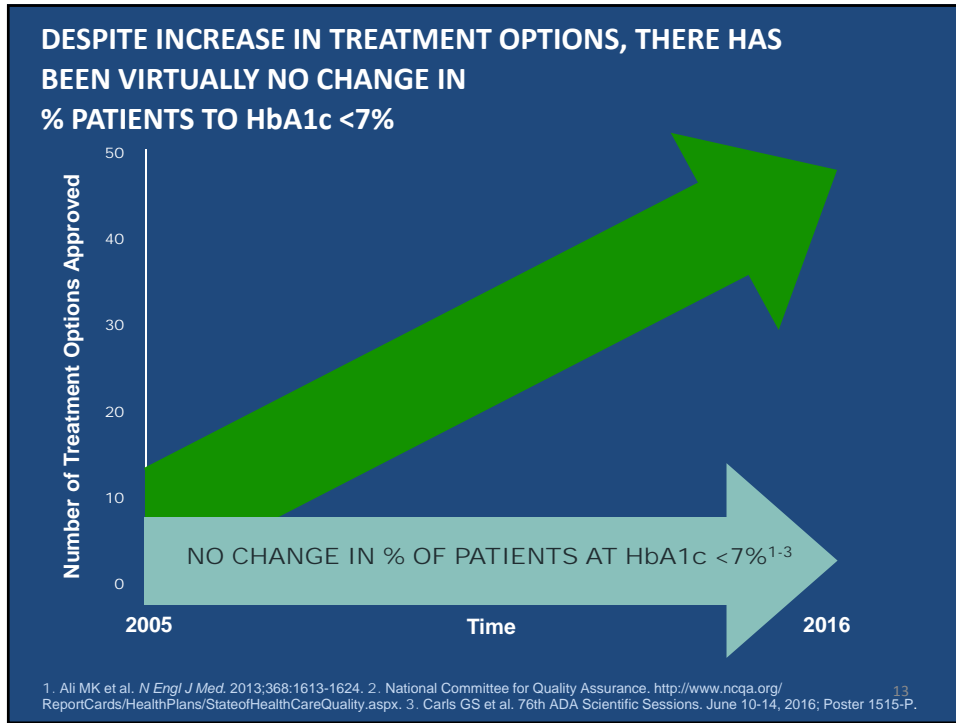
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## Treatment Options for Type 2 Diabetes

- American Diabetes Association recommends first-line therapy with metformin
- Many patients require more intensive dual or triple therapy
- Second line treatments can be any one of six different classes of medication
- No preference given for any class

American Diabetes Association. *Diabetes Care*. 2016;39(Supplement 1): S52-S59.





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**Advances in Diabetes Treatment and Contracting Strategies**

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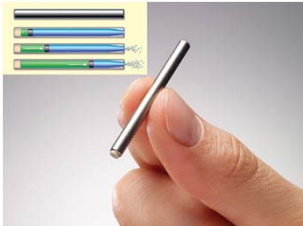
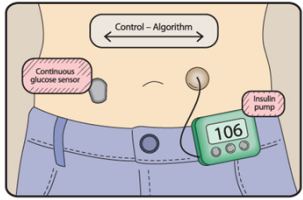
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- Medication delivery e.g. ITCA 650 Implant (exenatide)
- Artificial Pancreas
- Smaller pumps with CGM Sensors
- Outcomes data: empagliflozin, liraglutide
- New meds, basal insulins & analogs (and combos)
- Oral insulin delivery system
- Apps and more Apps
- Data sharing

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### Forum Findings: Evidence for Novel Treatments

- Need for comparative data to help understand the place in therapy for 2nd line (or 3rd line) treatment options
- Some medications have shown specific benefits (e.g. reducing cardiovascular outcomes and death), but it is often unclear whether this is a class or drug effect
- Data required by FDA for approval does not fill the gaps in evidence needed for managed care decision makers (e.g. comparative effectiveness with standard of care)
- Interest in a data repository of patient data to generate/evaluate RWE





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Outcomes that matter (beyond Hb1Ac) to managed care organizations when evaluating the evidence for novel diabetes treatments and tools

Top 10 Outcomes beyond HbA1c (in rank order)	Other outcomes of importance (>15% of respondents prioritized these as important outcomes)
Comparative effectiveness of treatments Hypoglycemia Time patient is within glycemic range Depression scores/mental health assessment Sleep time and quality Patient self-management assessment Hospitalization/ER visits Impact (improvement) to HEDIS and STAR measures Adherence 30-day readmissions	Blood pressure and cholesterol levels Quality of Life

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### Challenges in Outcomes Based Contract Measures

- Attribution - who are the patients that are part of the contract?
- Measure concerns
  - Variability – different for different payers (e.g. HbA1c < 9, < 8 or < 7) makes it challenging for clinicians
  - Operability – which patient, which measure, which goal, which health plan
- Patient Concerns – currently focusing mostly on patients with insurance, 90% of management is in the patient’s hands, financial toxicity is a factor
- Data management – lag in data, need real time data

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**Forum Findings: Harmonizing Metrics**

- Value-based contracting relies on metrics
- Heterogeneity of metrics poses challenges for providers and payers
- Standardize quality and value measures used in value-based contracting for use consistently throughout the health care system.
  - Use regional coalitions (made up of payers and care delivery systems) to develop consensus on which quality measures will be used to ease the burden on data integration and analysis.
- Consider the use of nonclinical measures that capture the impact of diabetes on patient wellness and function, including patient-reported outcomes.



**Innovations in Care Models - Impact on Quality**

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## Factors Affecting Adherence

- Affordability of treatment
- Treatment complexity
- Distrust of providers or treatments
- Inpatient vs. Outpatient formulary status creates confusion and complexity in care transitions
- Patient literacy issues
  - Health literacy, numeracy, understanding of benefit designs
- Longer duration of disease
- Personal challenges
  - Depression, stress, life challenges, changing behavior, etc.



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## Forum Findings: Adherence and Diabetes Care

- Major barrier to desired clinical outcomes
- Diabetes requires substantial behavior change
  - Patients must adhere to medication regimens, diet, exercise, self-monitoring of blood glucose
- Education and support to improve adherence are major targets for managed care interventions






**Key Opportunity: Leverage Data and Systems**

- Utilize EHR systems to tailor interventions
- Analyze and segment data to design population management strategies
- Factors to consider
  - Patient costs
  - Literacy, numeracy, and cultural
  - Treatment complexity
  - Incidence of adverse events (e.g., severe hypoglycemia)
  - Daily impact of diabetes on the patient's experience



**Key Opportunity: Care Model Innovations**

- Expansion of integrated care models
  - E.g., patient centered medical homes, accountable care organizations
- Facilitate greater direct patient interaction, including self-management education and prevention programs
  - Greater interaction with pharmacists and nurses
  - Behavior changes, improved self management
- Consider financial incentives to support patients between visits
  - Patient incentives (e.g., waived copays)
  - Provider incentives (e.g., payment for telemedicine, mHealth)

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## Integrated Care Support For The Person with Diabetes

### Key Focus

- Quality Measures- meaningful outcomes (ADL, falls, accidents, CV)
- Improving costs- to the patient (Drug costs and insurance costs)
- Delivery of care- individualize and adjust

**Quality Measures:** drives work but provides opportunity, drug ROI to patient, coordinated and delivered effectively

**Improving Costs:** providing alternatives, supporting adherence, annual assessments, short vs. long term costs

**Delivery of Care:** connected care, team approach, proactive planned care, patient driven, accountability

**Caution: Using surrogate markers to communicate care/outcome goals to patients is not patient centered, consider the patient's goals in your communications** 25

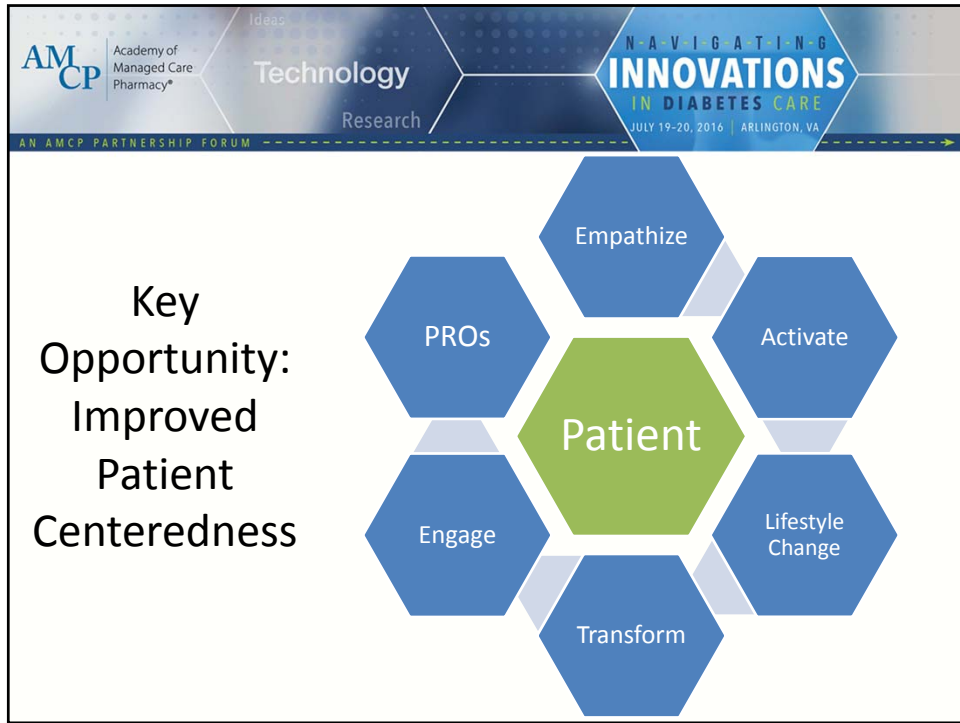




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## Key Opportunity: Support Pharmacists on Care Teams

- Greater support for collaborative practice agreements
  - Allow pharmacists to perform specific functions under protocol
- Expand opportunities for pharmacists to receive compensation for patient care services
- Consider quality metrics that measure team care





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## Navigating mHealth Products

- >165,000 digital health products
  - >1,000 for diabetes
- Need for clinical and scientific differentiation
- Need tools (e.g. process, methodologies) to evaluate mHealth products for potential benefit coverage

[http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Patient%20Adoption%20of%20mHealth/IIHI\\_Patient\\_Adoption\\_of\\_mHealth.pdf](http://www.imshealth.com/files/web/IMSH%20Institute/Reports/Patient%20Adoption%20of%20mHealth/IIHI_Patient_Adoption_of_mHealth.pdf)



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## FDA Regulation of mHealth Products

- FDA regulates mHealth products that
  - Meet the definition of a medical device and
  - Could pose a patient safety risk if it did not function properly (e.g., an app that controls insulin release)
  - For example: an app that controls an insulin pump would likely be subject to regulation.
- FDA uses same safety and effectiveness requirements for such products as for other medical devices
- FDA may include post marketing surveillance plans that monitor specific parameters
  - Cybersecurity issues
  - Smartphone issues such as compatibility across device platforms
  - reliability of operations through software upgrades

<http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>








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## Forum Findings: mHealth

1. Likely able to use a similar framework/monograph as pharmaceutical product reviews for mHealth solutions
2. Need to learn the language of the mHealth ecosystem
3. Likely need to consider unconventional study design (e.g., ecological momentary interventions, n-of-1) when evaluating or generating evidence
4. Recognize that drivers for mHealth include patients and innovators outside of usual development pathways (e.g., Nightscout, #DIYPS, Tidepool)
5. Need to better understand how mHealth solutions paid for
  - CMS Coverage Determination (Rx, OTC, DME), Medical, pharmacy, DME, Interest in a repository of mHealth tools

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## Tools to Evaluate mHealth Products

- Existing tools
  - WHO mHealth Evaluating Reporting and Assessment checklist
  - Mobile App Rating Scale
  - *Diabetes Spectrum* guide for the evaluation of diabetes mobile apps
- What's needed
  - Evidence-based guidelines from national organizations
  - Assessments of mHealth tools from unbiased nonprofits based on data and evidence
  - Central database of mHealth tools with crowd-sourced reviews and recommendations

Agarwal S, LeFevre AE, Lee J, et al. *BMJ*. 2016;352:i1174.  
 Ristau A et al. *Diabetes Spectrum*. 2013;26:211–5.  
 Stoyanov SR, Hides L, Kavanagh DJ, et al. *JMIR Mhealth Uhealth*. 2015;3:e27.





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## Patient Perspective

**Apart from helping to reduce costs, what is the most important thing your insurer could do to help improve your life with diabetes? (n=2,436)**

1. Increase coverage of drugs, devices, and other services (CGM, test strips, health and wellness programs, gym discounts, mental health, mHealth)
2. Make it easier for me to obtain the therapies I need (less red tape, helpful apps/websites)
3. Provide access to support or educational services (online and live classes, 24/7 nurse support)
4. Provide accurate information or advice about diabetes (tailored customer service, recipes, nutrition information)



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## Key Stakeholder Recommendations for Optimizing the Value of Advances in Diabetes Care



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- Develop a data repository to generate and evaluate real world evidence.
- Design clinical trials for novel diabetes treatments to include outcomes beyond A1c and use of active standard-of-care comparators.
- Standardize quality and value measures used in value-based contracting for use consistently throughout the health care system.
- Consider the use of nonclinical measures that capture the impact of diabetes on patient wellness and function, including PROs (e.g. sleep quality).



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- Implement strategies and payment models that increase pharmacist engagement in patient care teams.
- Consider use of evidence-based financial incentives for patients that have been shown to stimulate engagement.
- Develop a central repository of information about various mHealth tools, including data regarding the impact on outcomes.
- Use regional coalitions (made up of payers and care delivery systems) to develop consensus on which quality measures will be used to ease the burden on data integration and analysis.



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- 3 main panels organized by FDA CDER
  - Regulatory Perspective; Patient and Patient Advocacy Perspective; Industry Experience in Outcome Measures for Diabetes
- Takeaways
  - Beyond A1c: QOL, technology, CER, advances necessary to improve outcomes for people with diabetes
  - Use of PROs to measure success of therapy, both in clinical trials and on daily basis
  - Patient involvement in clinical trials
- Coming down the pike...
  - Framework to establish appropriate standardized measures and surrogates for outcomes, esp PROs and validated instruments (via FDA Drug Quantification Pathways?)
  - FDA activity
  - Other related activity

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### Outcomes that Matter (beyond Hb1Ac) to Patients

Not necessarily in rank order

*Time-in-range, avoidance of hypoglycemia and PROs rise to the top*

Direct blood glucose metrics: Avg. glucose + variability in/around ranges  
 Health-related QOL: Energy, mood, cognitive functioning, sleep  
 Diabetes burden, convenience/less hassle/ease of management, treatment satisfaction, side effects  
 Weight change, weight management, weight loss  
 Emotional well-being, depression, psychosocial scores, financial stress, family impact  
 Fasting blood sugars or insulin sparing (medications that reduce insulin requirements)  
 Outcomes that could improve precision with which medications are prescribed  
 Biomarkers  
 Reduce fear of hypo, nighttime lows, ER visits, death, etc.

Patient Video: [www.youtube.com/watch?v=QTi2qdOtb4w](http://www.youtube.com/watch?v=QTi2qdOtb4w)

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