Disclosure to Participants

- Notice of Requirements For Successful Completion
  - Please refer to learning goals and objectives
  - Learners must attend the full activity and complete the evaluation in order to claim continuing education credit/hours
- Conflict of Interest (COI) and Financial Relationship Disclosures:
  - Presenter: Heather Young, PhD, RN, FAAN – No COI/Financial Relationship to disclose
  - Presenter: Maria Ibarra – No COI/Financial Relationship to disclose
- Non-Endorsement of Products:
  - Accredited status does not imply endorsement by AADE, ANCC, ACPE or CDR of any commercial products displayed in conjunction with this educational activity
- Off-label Use:
  - Participants will be notified by speakers to any product used for a purpose other than for which it was approved by the FDA and/or FDA.

MEANINGFUL PATIENT ENGAGEMENT IN RESEARCH: PCORI STUDY

Patient Centered Outcome Research Institute (PCORI)

Mission: PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader healthcare community.

Patient Centered Outcome Research Institute (PCORI)

- PCORI was established as a provision of the Affordable Care Act
- First research funded in December 2012
- Board of Governors, including Director of AHRQ and Director of NIH and stakeholders across sectors
- Methodology Committee
- Funded by federal general fund and fees assessed on Medicare and private insurers
- Expect $3.5 billion in funding through 2019 at about $650 million/year
**P^2E^2T^2 Program to Improve Health in Diabetes**

**Budget:** $2,098,246  
**Project Period:** 3 years

**Overall Goal:** Develop and evaluate an innovative program that uses nurse health coaching, motivational interviewing techniques, and wireless sensor and mobile health (mHealth) technology.

---

**Project Team: Investigators**

- Heather Young, PhD, RN (Principal Investigator)  
- Jay Han, MD (Co-Principal Investigator)  
- Madan Dharmar, MBBS, PhD  
- Sheridan Miyamoto, PhD, RN  
- Yajarayma Tang-Feldman, MA  
- Thomas Balsbaugh, MD  
- Bridget Lovich, RN, MSN, CDE  
- Sarina Fazio, MS, RN (Project Manager)  
- Stuart Henderson, PhD

---

**Collaborators**

- UC Davis Health System  
- Primary Care Clinics  
- Center for Information Technology Research in the Interest of Society

---

**Chronic Disease**

- One in every two adults in the U.S.  
- Now surpasses communicable diseases in prevalence globally  
- 75 percent of healthcare costs  
- Common lifestyle factors: physical activity, diet, smoking, alcohol, medication management  
- Implications for symptoms and function  
- Highly modifiable and amenable to self-management

---

**Diabetes Mellitus**

- One of the top 5 chronic diseases  
- 29 million - almost 10% of U.S. Population (2010)  
- Modifiable behavioral risk factors (physical inactivity, poor eating and sleep habits, obesity and smoking)  
- 48.3 million affected (projected 2050)

---

**Initiative for Wireless Health and Wellness – Technology Foundation**

- Developed a platform that accepts patient-generated data from sensors  
- Explored patient preferences for use of technology in health care  
- Determined that data on platform should be visually concise, intuitive, and meaningful so patients and providers can work together to promote health behavior change through goal setting
Improving Health in Diabetes

• Motivational Interviewing
  ❖ Improve self-efficacy
  ❖ Support behavioral changes
  ❖ Enhancing goal setting and problem solving capacity
  ❖ Lead to improved self-management, and glycemic outcomes

Technology in Patient Engagement

❖ 91% of U.S. adults own a cell phone
❖ 56% of U.S. adults have smartphones
❖ Seven in ten U.S. adults track a health indicator
❖ 62% of U.S. adults with two or more chronic conditions track a health indicator
❖ Of those, 45% have diabetes

Drivers and Barriers for Use

FUNCTIONALITY
Intuitive design
Ease of use

CUSTOMIZATION
Control over what data is shared
Personalized feedback

INTEGRATION
Work with existing tech
Linked to health data

Thrust
Reliable data
Data access

Nurse Coach Dashboard

Data: Blood Pressure
Goal: 120/80
Actual: 126/83
Change: +4/+3

MEANING
You have trouble meeting your activity goals on Mondays and Tuesdays. What happens on those days? What changes might you make?

Activity levels seem to be linked to your sleep quality at night:

Certain night time meals and alcohol intake appear to impact sleep quality and mood

Your blood pressure has improved due to changes you have made to your diet and activity in the past 3 months!

Connected Mobile Health

Overall Goal: Lose 5 lbs over 2 months by increasing activity (s): Achieve >10k steps per day; Limit calories
SMART Goal: Achieve >10k steps per day. Limit calories to less than 1,500 calorie per day. Drink at least 60 fluid oz at least every day.

Drivers and Barriers for Use

FUNCTIONALITY
Intuitive design
Ease of use

CUSTOMIZATION
Control over what data is shared
Personalized feedback

INTEGRATION
Work with existing tech
Linked to health data

Thrust
Reliable data
Data access

Nurse Coach Dashboard

Data: Blood Pressure
Goal: 120/80
Actual: 126/83
Change: +4/+3

MEANING
You have trouble meeting your activity goals on Mondays and Tuesdays. What happens on those days? What changes might you make?

Activity levels seem to be linked to your sleep quality at night:

Certain night time meals and alcohol intake appear to impact sleep quality and mood

Your blood pressure has improved due to changes you have made to your diet and activity in the past 3 months!
**Project Goal and Specific Aims**

**Goal:** Develop and evaluate an innovative program that uses nurse health coaching with motivational interviewing techniques, and wireless sensor and mobile health (mHealth) technology.

- **Aim 1:** Refine and finalize the intervention elements (nurse coaching, wireless sensor technology and mHealth framework, relevant outcomes) with stakeholders.
- **Aim 2:** Integrate patient-generated goals and sensor data into a mHealth dashboard linked back into the clinical record.
- **Aim 3:** Evaluate the effectiveness of the P²E²T² Program on diabetes management.

**Patient Recruitment and Enrollment**

**UC Davis Clinic Sites:**
- Hospital Based Primary Care Clinic
- Folsom Primary Care Clinic

**Clinical Trial:**
- Chronic Disease Management
- P²E²T² Program

**P²E²T² Intervention**

- Planning Conference Call with Nurse Coach
  - Establish priority health issue and desired goals
- Technology Meeting (In-Person)
  - Orientation and training
- Five bi-weekly support calls
  - Review progress and discuss approaches
  - Review Patient Generated Data
- Final Action Plan and Follow-up with Provider
  - Summarize goals and progress
  - Communicate to Provider

**Patient Outcomes**

<table>
<thead>
<tr>
<th>Self-Efficacy</th>
<th>Diabetes Empowerment Scale – Short Form (DES-SF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readiness to Change</td>
<td>Readiness to Change Survey</td>
</tr>
<tr>
<td>Clinical Indicators</td>
<td>Salivary Cortisol &amp; HbA1C</td>
</tr>
<tr>
<td>Quality of Life</td>
<td>Perceived Stress Scale (PSS)</td>
</tr>
<tr>
<td></td>
<td>Patient Health Questionnaire Depression Scale-9 (PHQ-9)</td>
</tr>
<tr>
<td></td>
<td>World Health Organization Disability Assessment, Schedule 2.0 (WHODAS 2.0)</td>
</tr>
</tbody>
</table>
Stakeholder Engagement

- Patient Advisory Workgroup
- Provider Advisory Workgroup
- Technology Advisory Workgroup

Patient Advisory Board

- Ms. Diane Goodman (co-chair)
- Dr. Margaret Hitchcock (co-chair)
- Ms. Maria Ibarra
- Mr. Michael Lawson
- Mr. Tarunesh Singh
- Mr. Joseph McCarthy
- Mr. Eric Bowser

Patient Advisory Board Responsibilities

- Advise the research team about study design, approach and outcomes to be measured
- Identify gaps important to you in existing care
- Present your views about patient preferences for the use of technology and integration into care
- Pilot/test the technology and platform- provide feedback
- Attend quarterly meetings (~2 hours each)
- Attend conferences to learn about latest technology that may be useful in the project
- Assist team to interpret data and disseminate research findings

Patient Involvement in Research

Ms. Maria Ibarra

- Introduction to research – participant in study by Dr. Deborah Greenwood
- How research improved management of diabetes
- Reasons to participate as an advisor
- Description of the experience of advising

Ms. Maria Ibarra’s Story


Provider Advisory Board

- Antonio B Balatbat, MD (Mercy Hospital, Dignity Health)
- Tom Balduffield, MD (UC Davis Health System)
- Victor Baguio, MD (UC Davis Medical Group, Folsom)
- Deborah Greenwood, PhD, RN, MEd (American Association of Diabetes Educators)
- Patrick Krasovec, MD, MPH (UC Davis Health System)
- Bridget Leach, RN, MSN, CDE (UC Davis Health System)
- Barbara Pellegrino, RN, MSN (Dignity Health)
- Patrick Patterson, MD, MPH (UC Davis Health System)
- Jonathan Wallack, RN, MSN (Kaiser Permanente)
### Technology Advisory Board
- Nina Ameria, PhD (Department of Computer Sciences, UCD)
- Thomas Nestel, MD (Center for Health and Technology)
- Kent Anderson, MS (Clinical and Translational Science Center)
- Nicholas Anderson, PhD (Clinical & Translational Science Center)
- Steven Shan, MD (UCD Health System)
- Sunil Ram, MBBS, MD (UCD Health System)
- Michael Munoz (UCD Health System)
- Jana Katz-Bell, MPH (UCD Health System)
- Scott MacDonald, MD (UCD Health System)
- Nicholas Anderson (Clinical & Translational Science Center)
- Mathew Lange (Institute for Wireless Health & Technology)
- David A. Linderman, PhD (CITRIS)
- Keian Hsia, PhD (Department of Computer Sciences, UCD)
- Scott Macchiar, MD (UCD Health System)
- Michael Munoz (UCD Health System)
- Anil Pandit, PhD (Department of Computer Sciences, UCD)
- Ted Stick, MBA (UCD Health System)
- Danel Wieland, PhD, MPH, RN (Kaiser Permanente)

### PCORI Contract Management
- Program Officer, Contracts Management, Patient Engagement Officer
- Team responsible for specific deliverables and due dates (milestones) as stipulated in the original approved application
- Milestone achievement is jointly assessed by Scientific, Patient Engagement and Contracts Management staff
- Payment is made contingent on approval of successful and timely completion of contract milestones
- Quarterly meetings reviewing progress

### Patient and Stakeholder Engagement
- Engagement at every step of the process
- Initial framing of questions, identifying important issues, study design
- Proposal included data from stakeholders throughout
- As background and in informing the design and methods
- Formal roles for stakeholders
- Advisory boards with agenda that are tied to the milestones and deliverables
- Payment of patients
- For time on board as well as for travel for learning and dissemination

### Questions and Discussion
Thank you!