Agenda

WHY UNDERSTANDING BEHAVIORS CAN UNLOCK CARE SUCCESS

- 8.45 - 9.00
  Welcome coffee

- 9.00
  Kick-off

- 9.00 - 9.10
  Introduction by Alexandra Rocca, Global Head of Communications

- 9.10 - 9.20
  Reducing the efficacy gap between the clinical and real world settings, the impact of patient behavior in clinical outcomes.
  *Anne Beal, M.D., M.P.H, Global Head of Patient Solutions, Sanofi*

- 9.20 - 9.35
  How Sanofi is active in the space of Real World Evidence?
  *Bernard Hamelin, M.D., Global Head Medical Evidence Generation, Sanofi*

- 9.35 - 9.50
  Evidation: a concrete case study to understand the technology behind behavioral science
  *Christine Lemke, Co-founder and President, Evidation Health*

- 9.50 - 10.20
  Q&A with the floor

- 10.30
  Close
Leveraging behavioral science to improve health outcomes

Anne C. Beal, MD, MPH Global Head of Patient Solutions, Patient Solutions Unit
Pharma is facing unprecedented change

In the real world, when people have to manage their conditions, they’re not skilled at self-management, nor are they utilizing their treatments appropriately

• **50% of health outcomes** are determined by behavior, yet physicians are not well trained for this part of their job¹

• **30% of people** don’t fill prescriptions for chronic conditions²

• **50% of people** with a chronic disease don’t take their medication as prescribed³

Helps people to achieve improved health outcomes by supporting optimal utilization of Sanofi products and services and enhancing their activation and self-management

¹Bipartisan Policy Center, 2012; Volpp, Kevin. NEJM Catalyst, 2016
²Tanblyn et al. Annals of Internal Medicine, 2014
³WHO, 2003
Leveraging behavioral science to close the gap between real world effectiveness & efficacy...

Behavioral Science can address clinical inertia, patient activation and non-adherence which are critical to improving outcomes

**FACTORS CONTRIBUTING TO GAP:**

**PATIENT**
- self-management, co-morbidities, concomitant medications...

**PHYSICIAN**
- patient interaction, care coordination, Rx behavior...

**SYSTEM**
- access (formulary, reimbursement, quality of care, affordability…)

**CONTEXTUAL**
- SES, zip code, race, ethnicity, social support, family, etc.

Medical can bridge this gap through evidence-based interventions by:

- Understanding patient factors behind the gap and associate them with outcomes
- Designing interventions to influence key factors that will lead to improved outcomes

*Relative scale of impact for patient factors, HCP, health system, and contextual factors varies case by case. Broader results/outcomes differences in clinical trial efficacy and real world effectiveness may vary on a case by case basis.*
Hibbard: Patient Activation Measure (PAM)

LEVEL 1
Overwhelmed & disengaged
10-20%

LEVEL 2
Becoming aware, but still struggling
10-20%

LEVEL 3
Taking action
25-30%

LEVEL 4
Maintaining behaviors
20-25%

0-100 point scale

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Hibbard: Activation and Medication Adherence

Use of Medications by Level of Activation

Source: 2004 National Sample

Source: Sanofi Press Breakfast on Behavioral Science - 22 September 2017 - Paris
Diabetes Control With Reciprocal Peer Support Versus Nurse Care Management

A Randomized Trial

Michele Helsler, MD, MPA; Sandeep Vijan, MD, MS; Fatma MakkI, MPH; and John D. Piette, PhD

Background: Resource barriers complicate diabetes care management. Support from peers may help patients manage their diabetes.

Objective: To compare a reciprocal peer-support (RPS) program with nurse care management (NCM).

Design: Randomized, controlled trial. (ClinicalTrials.gov registration number: NCT00320112)

Setting: 2 U.S. Department of Veterans Affairs health care facilities.

Patients: 244 men with hemoglobin A1c (HbA1c) levels greater than 7.5% during the previous 6 months.

Measurements: The primary outcome was 6-month change in HbA1c level. Secondary outcomes were changes in insulin therapy; blood pressure, and patient reports of medication adherence, diabetes-related support, and emotional distress.

Intervention: Patients in the RPS group attended an initial group session to set diabetes-related behavioral goals, receive peer communication skills training, and be paired with another age-matched peer patient. Peers were encouraged to talk weekly using a telephone platform that recorded call occurrence and provided reminders to promote peer contact. These patients could also participate in optional group sessions at 1, 3, and 6 months. Patients in the NCM group attended a 1.5-hour educational session and were assigned to a nurse care manager.

Results: Of the 244 patients enrolled, 216 (89%) completed the HbA1c assessments and 231 (95%) completed the survey assessments at 6 months. Mean HbA1c level decreased from 8.02% to 7.73% (change, −0.29%) in the RPS group and increased from 7.93% to 8.22% (change, 0.29%) in the NCM group. The difference in HbA1c change between groups was 0.58% (P = 0.004). Among patients with a baseline HbA1c level greater than 8.0%, those in the RPS group had a mean decrease of 0.88%, compared with a 0.07% decrease among those in the NCM group (between-group difference, 0.81%; P < 0.001). Eight patients in the RPS group started insulin therapy, compared with 1 patient in the NCM group (P = 0.020). Groups did not differ in blood pressure, self-reported medication adherence, or diabetes-specific distress, but the RPS group reported improvement in diabetes social support.

Limitation: The study included only male veterans and lasted only 6 months.

Conclusion: Reciprocal peer support holds promise as a method for diabetes care management.

Primary Funding Source: U.S. Department of Veterans Affairs Health Services Research and Development Service.

Advice and Input, Behavioral Science Toolkit

1 STRATEGIC AREAS OF IMPROVEMENT
(ex: improve adherence, develop patient self management skills etc)

1. Selection of the strategic area of improvement
2. Recommendations for segmentation
3. Operational objectives highlighted
4. Exploration of Tips & Tools, Case studies and References

2 PRACTICAL OBJECTIVES
(ex: improve patient enrolment, physician engagement, develop tool personalization etc)

1. Recommendations for segmentation
2. Selection of the operational objective
3. Exploration of Tips & Tools, Case studies and References

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Pharma is facing unprecedented change

- Physicians seeking peer-peer interaction
- Vocal patient populations
- Rising development costs
- Greater requirements for post-marketing evidence
- Shifting global demographics
- Increasing safety concerns
- Tougher regulatory controls; societal expectation
- Digital Health Revolution
- Payors pushing for Real World Evidence
- Increased transparency expectations

Evidence generation needs to evolve to better understand and improve patient outcomes
Evidence requirements are increasing

Development       Growth Phase       Mature Phase

- Understand standard of care
- Patient recruitment
- Trial design
- Post-marketing commitments (safety etc.)
- Budget impact
- Utilization/prescribing patterns
- Adherence
- Head to head safety, comparative effectiveness
- Differentiation in sub-populations
- Target populations
- Long-term safety, clinical outcomes
- Effects of switching on outcomes
- Usage difference
- Differentiate with or vs. protected formulation

- New Indication/Formulation
- New Competition
- Long-term safety, clinical outcomes
- Long-term safety, clinical outcomes
- Usage difference
- Differentiate with or vs. protected formulation

- Development
- Pricing Review
- Launch
- Sub-mission

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Evidence generation methodologies

Randomised Clinical Trial  Pragmatic Clinical Trial  Observational Study
Real World Evidence is based on data from multiple sources

Source: jama, 22 May 2014
What we do: methodologies we use and partners we work with

Methodologies

**Traditional analytics**
- Traditional RWE statistics
- Meta-analysis
- Propensity-score matching
- OMOP data modelling

**Advanced analytics**
- Predictive modelling
- Unsupervised clustering
- Machine learning
- Rule extraction
- Model bootstrapping
- Natural Language Processing (NLP)

Partnerships

[Logos of various companies]
New data, new platforms, and new analytics make new insights possible
Quantifying impact of behaviors on health outcomes
Evidation Health is a technology and services company that helps individuals and healthcare companies understand the link between everyday behaviors and health outcomes.
Patients and their outcomes have been characterized by using limited data sets based on what was visible to the system.

**DATA POINTS**

Visible & Episodic  
*(in clinical settings)*

Invisible & Continuous  
*(in real life)*

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Evidation captures previously invisible everyday behavior data and combines it with traditional clinical data sets to understand behaviors and health outcomes.

### REAL WORLD PRACTICE
- **Trials**
  - Clinical trial data
- **Provider system registries**
- **EHR data**
- **Pharmacy and medical claims**

### REAL LIFE OF THE PATIENT
- **Behavior data**
  - (activity, sleep, diet, social media, cognition, technology interaction, etc.)
- **Patient-reported metrics**
  - (symptoms, outcomes, anytime, anywhere)
- **Contextual data**
  - (weather, pollen count, geolocation, census data, occupation, etc.)

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This explosive new data source - **behavior data** - shows promise to quantify health outcomes more quickly and observe new effects.
It requires a scalable system to connect directly with individuals to gather, contextualize, and combine behavior data with clinical data.

>1.5 BILLION
new activity events recorded each month

>3 MILLION
patients on the platform, across multiple therapeutic areas
…and services combined with a platform to reach individuals for permission-based data sharing

Find people 10x faster
Design research studies
Execute privacy safe, virtual study protocols
Interpret and deliver results
Peer review standard
## Results: faster, more proactive care

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<thead>
<tr>
<th>Digital Biomarker Discovery</th>
<th>Digital Evidence Generation</th>
<th>Digital Biomarker Discovery</th>
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<tbody>
<tr>
<td><strong>Challenge</strong></td>
<td>Assess the effectiveness of medication adherence application</td>
<td>Quantify cognitive decline through voice and speech signals</td>
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<tr>
<td>Understand medication adherence in patients with diabetes</td>
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<tr>
<td><strong>Data inputs</strong></td>
<td>Connected monitors, engagement data, patient reported outcomes</td>
<td>Voice, speech, clinical data</td>
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<td>Weight, activity, adherence measured through pharmacy claims data</td>
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<tr>
<td><strong>Results</strong></td>
<td>Recruited and observed 400+ patients, recruited 10x faster</td>
<td>Predict cognitive decline scores solely based on voice and speech (\text{(research embargoed)})</td>
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<td>Discovery of behavior pattern that led to adherence drop</td>
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<td><strong>Application</strong></td>
<td>Evidence package for use in market commercialization</td>
<td>Improved screening, monitor therapeutic impact (e.g. oncology)</td>
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<td>Monitor patients and deliver diabetes education at right time</td>
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Questions

September 2017

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Thank you
Q&A