Opportunities for Patient-Centric CV Healthcare through Retail and Nontraditional Industries

Mar 4, 2024

Dylan L. Steen MD MS
Disclosures

- Consultant: Sanofi, Esperion
- CEO/Cofounder: High Enroll, LLC
- Grant: The Kroger Company, a large U.S. supermarket chain.

Topics

- Industry observations and opportunity
- Choosing a retailer and strategy
- SuperWIN Trial
- Post-SuperWIN activity
- Final thoughts
Topics

- Industry observations and new opportunity
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Value of Research from Academic/Industry Partnerships

- Example: Lipitor (Pfizer)

1. High-intensity statin therapy should be initiated or continued as first-line therapy in women and men \(\leq 75\) years of age who have \textit{clinical ASCVD*}, unless contraindicated.

A (Strong)
1) How did it Happen? History of Pharmaceutical Industry

Cultural Shift in how Pharmaceutical Industry Pursued Its Purpose:
- R&D Investment
- Hiring Top-quality Scientists
- Collaboration

George Merck

2) What is Needed Now? New Partners for Unsolved Challenges

Expansion of Healthcare Beyond Traditional System:
- Access, Convenience, Engagement, Effectiveness
- Testing Platforms and Rigorous Studies Needed

Hospitals
Clinics

Grocery/Supermarket Industry

Problem:
- Supermarkets and grocery stores represent a highly competitive, low-margin, and slow growth market.

Goals:
- Increase store traffic, cross- and up-sell products, improve customer experience, and improve brand.
Retail-based Healthcare

Figure: Increasing Number of US Retail Clinics

Source: Drug Channels Institute, 2017

Increasing Retail Clinic Use

Figure: 2015 Retail Health Clinic Visits per 1,000 Visits by Age

Source: Blue Cross Blue Shield 2017
Retail Clinic Visits: Simple/Episodic Care

Figure: Reasons Cited for Visiting Retail Clinic

Disruption in the Retail Industry

Opportunity to Engage Retail Industry in Research

Amazon Deal for Whole Foods Starts a Supermarket War

Macy's to Close 100 Stores Beginning Next Year to Refocus on Online
Opportunity for Research Studies

Example: CVS Health – BWH/UPenn

The New England Journal of Medicine

ORIGINAL ARTICLE

Randomized Trial of Four Financial-Incentive Programs for Smoking Cessation

Scott D. Halpern, M.D., Ph.D., Benjamin French, Ph.D., Dylan S. Small, Ph.D., Kathryn Saunders, Ph.D., Michael D. Hargreaves, M.B.B.S., James Audin-McGowan, Ph.D., George Lieberman, Ph.D., Tashan A. Rimmer, M.D., J.D., David A. Asch, M.D., M.B.A., and Kevin G. Volpp, M.D., Ph.D.

JAMA Internal Medicine | Original Investigation

Effect of Reminder Devices on Medication Adherence
The REMIND Randomized Clinical Trial

Wesley Y. Chou, M.D., Ph.D., Ali A. Kharrazi, M.D., Patrick M. Eccleston, Ph.D., M.B.B.S., Charnanee Gholson, M.P.H., Angela Y. Tang, M.S., Nafidah F. Khan, BS, Troy A. Bremner, MD, JD, MPH, Olivia M. Mathy, M.D., and William K. Hersh, M.D., M.S., Michelle A. Fattah, Ph.D.
Topics

- Industry observations and opportunity
- **Choosing a retailer and strategy**
  - SuperWIN Trial
  - Post-SuperWIN activity
  - Final thoughts

Kroger Company: Ideal Partner

Largest U.S. Supermarket Chain

Infrastructure for More Complex Interventions:

- Accessible and convenient physical store footprint
- Full grocery inventory and pharmacy
- In-store health professionals (e.g. dietitians, nurses)
- Growing customer-centric model (e.g. mobile)
- Big data and analytics expertise

Partnership Research Foci:

- Chronic disease management
- Randomized, clinical trials
- Establishing new standards of conduct (e.g. retention)
Building Multicomponent Interventions

Trial 1
- Diet

Trial 2
- Diet + Medications

Trial 3
- Diet + Medications + Monitoring

Each trial adds a new component, while incorporating the findings from the previous trial.

Vision for Integrated Healthcare

Research Partner: UC Primary Care Network

Key Attributes:
- Goal is value (i.e. outcomes/cost): CPC+
- Alignment with potential benefits of retailers
- Parallel ambulatory innovation efforts
- Provides access to comprehensive payer database
- Provider study recruitment/retention support
Topics

- Industry observations and opportunity
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- **SuperWIN Trial**
- Post-SuperWIN activity
- Final thoughts

**SuperWIN Trial**
*(Supermarket and Web-Based Intervention Targeting Nutrition)*

**ACC 2022:**
Late-breaking Clinical Trial

* Dylan L. Steen M.D., M.S., Robert N. Helsley, Ph.D., Deepak L. Bhatt, M.D., M.P.H., Eileen C. King, Ph.D., Suzanne S. Summer, Ph.D., R.D.N., Matthew Fenchel, M.S., Brian E. Saelens, Ph.D., Mark H. Eckman, M.D., M.S., Sarah C. Couch, Ph.D., R.D.N.*
Background

Despite guideline recommendations, 75% of Americans have poor dietary quality.

In 2019, an AHA Scientific Advisory requested “immediate action” to address this gap. Specifically:

• Sponsored research with retailers (e.g. supermarkets)
• Studies of online shopping to promote healthier purchases
• Studies of nutrition applications

Bundy JD, et al. JAHA. 2021

Training Research Coordinators
(Kroger Dietitians)

Training Session: March 2019
### Dietary Education

<table>
<thead>
<tr>
<th>Control</th>
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**Randomized 1:2:2**

- **Dietary Education**
  - Purchasing data-guided, "in the aisles" education (6 sessions- 60min each)
  - Stepwise introduction and training on technologies (e.g., online shopping)
Individualized Dietary Review

**Daily Dietary Snapshot**

- **Average**: Calories 1782, Sodium 3322, Saturated Fat 22
- **DASH Friendly?**: Yes
- **DASH Friendly Servings**

**Food Name** | **Daily Servings** | **DASH Friendly?**
--- | --- | ---
Avocado, whole or pulp | 0.33 | Yes
Bread, beet, multigrain, regular | 0.17 | Yes
Bread, pumpkin with nuts | 0.32 | No
Cheese Sandwiches: Cheese sandwich | 0.33 | No
Cheese Sandwiches: meat/cheese or cheese, bread, wheat | 0.14 | No
Cheese Sandwiches: whole wheat, whole grain, regular, commercial | 0.67 | Yes

Total | 28.59

Dietary Education

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- **Strategy 1**: Purchasing data-guided, "in the aisles" education (6 sessions- 60min each)
- **Strategy 2**: Stepwise introduction and training on technologies (e.g., online shopping)
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### Individualized Purchase Review

(Both Strategies 1 and 2)

**Example**

- Spend Amount For Fruits and Vegetables (F/V) per visit (two week intervals)
- Item Description Info
  - Item (Single or Bulk)
  - Spend Amount
  - Count

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Spend Amount</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blueberries</td>
<td>$4.12</td>
<td>1</td>
</tr>
<tr>
<td>Broccoli</td>
<td>$3.20</td>
<td>1</td>
</tr>
<tr>
<td>Carrots</td>
<td>$0.99</td>
<td>1</td>
</tr>
<tr>
<td>Cauliflower</td>
<td>$2.50</td>
<td>1</td>
</tr>
<tr>
<td>Cheddar Cheese</td>
<td>$7.99</td>
<td>1</td>
</tr>
<tr>
<td>Eggs</td>
<td>$3.20</td>
<td>1</td>
</tr>
<tr>
<td>Spinach</td>
<td>$4.12</td>
<td>1</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>$2.50</td>
<td>1</td>
</tr>
<tr>
<td>Tuna</td>
<td>$4.99</td>
<td>1</td>
</tr>
<tr>
<td>Watermelon</td>
<td>$3.20</td>
<td>1</td>
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<td>Zucchini</td>
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- Purchasing data-guided, "in the aisles" education (8 sessions- 60min each)
- Stepwise introduction and training on technologies (e.g., online shopping)
"In the Aisles" Education
(Both Strategies 1 and 2)

Performed each visit
- Provides education (e.g. label reading)
- Sets goals and action plans (e.g. trying new foods)

Harnesses dietitians’ expertise
- Knowledge of the store layout and its inventory
- Guided by customer preferences/purchases

Dietary Education

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**Stepwise Online/Digital Intervention**

1) Online shopping with store pick-up or home delivery.

2) Supporting better food choices
   - Kroger’s OptUP App

3) Meal planning/recipe-building
   - Yummly Website/App
Hypothesis Testing

Two tests for DASH score change (baseline to 3 months):

1. **What is the efficacy of data-guided, in-store teaching?**
   Strategies 1 and 2 versus Control ("S1/S2 vs. Control")
   
   If \( p < 0.05 \), then

2. **What is the efficacy of online shopping and nutrition apps?**
   Strategy 2 versus Strategy 1 ("S2 vs. S1")

**DASH score:**
- Measure of DASH diet adherence
- Range 0-90
- Increased score = increased adherence

SuperWIN Trial Profile

**Screened by Phone and Entered Run-in:**
N=486

- Excluded During Run-in or at Randomization Visit: N=219
  - Did not complete assessments: N=44
  - Participant choice: N=33
  - Did not meet BP, BMI, and/or other biometric criteria: N=30

**OVERALL COHORT: N=247**
## Baseline Characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control (n=46)</th>
<th>Strategy 1 (n=100)</th>
<th>Strategy 2 (n=101)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age - mean - yr</strong></td>
<td>56.2 (11.4)</td>
<td>57.0 (10.7)</td>
<td>55.8 (11.0)</td>
</tr>
<tr>
<td><strong>Female - %</strong></td>
<td>69.6%</td>
<td>68.0%</td>
<td>70.3%</td>
</tr>
<tr>
<td><strong>Race - %</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>13.0%</td>
<td>23.0%</td>
<td>21.8%</td>
</tr>
<tr>
<td>White</td>
<td>78.3%</td>
<td>73.0%</td>
<td>71.3%</td>
</tr>
<tr>
<td><strong>Household annual income ≥$125,000 - %</strong></td>
<td>28.3%</td>
<td>37.0%</td>
<td>39.6%</td>
</tr>
<tr>
<td><strong>Children in the household – mean (SD)</strong></td>
<td>0.33 (0.67)</td>
<td>0.43 (0.89)</td>
<td>0.42 (0.89)</td>
</tr>
<tr>
<td><strong>Prior myocardial infarction or stroke - %</strong></td>
<td>10.9%</td>
<td>7.0%</td>
<td>5.0%</td>
</tr>
<tr>
<td><strong>Hypertension medications - %</strong></td>
<td>67.4%</td>
<td>77.0%</td>
<td>72.3%</td>
</tr>
<tr>
<td><strong>Blood pressure- mean (SD) - mm Hg</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systolic</td>
<td>130.0 (16.4)</td>
<td>129.8 (18.6)</td>
<td>128.4 (14.9)</td>
</tr>
<tr>
<td>Diastolic</td>
<td>85.7 (11.1)</td>
<td>82.1 (11.6)</td>
<td>83.4 (10.4)</td>
</tr>
<tr>
<td><strong>Body mass index- mean (SD) - kg/m²</strong></td>
<td>33.8 (7.2)</td>
<td>34.0 (7.9)</td>
<td>32.9 (8.1)</td>
</tr>
<tr>
<td><strong>Hypercholesterolemia medications - %</strong></td>
<td>43.5%</td>
<td>47.0%</td>
<td>36.6%</td>
</tr>
<tr>
<td><strong>Non-HDL cholesterol - mean (SD) - mg/dl</strong></td>
<td>107.0 (32.5)</td>
<td>115.2 (37.0)</td>
<td>112.5 (35.3)</td>
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Impact of COVID-19 on SuperWIN

Education Visit Attendance

![Graph showing the impact of COVID-19 on SuperWIN's education visit attendance.]

Impact of COVID-19 on SuperWIN

Education Visit Attendance

![Graph showing the impact of COVID-19 on SuperWIN's education visit attendance.]
### DASH Changes at 3 months

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<th>Overall Cohort</th>
<th>Control (N=46)</th>
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<tr>
<td>At baseline</td>
<td>45.2 (42.0, 48.4)</td>
<td>44.4 (42.0, 46.8)</td>
<td>43.2 (40.8, 45.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>At 3 months</td>
<td>51.0 (47.6, 54.4)</td>
<td>53.1 (50.6, 55.5)</td>
<td>55.6 (53.2, 58.1)</td>
<td></td>
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<tr>
<td>DASH Change</td>
<td>5.8 (2.5, 9.2)</td>
<td>8.6 (6.4, 10.8)</td>
<td>12.4 (10.3, 14.6)</td>
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Endpoints are reported as least-squares means (95%CI).
## DASH Changes at 3 months

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<td>5.8 (2.5, 9.2)</td>
<td>8.6 (6.4, 10.8)</td>
<td>12.4 (10.3, 14.6)</td>
<td>4.7 (0.9, 8.5)</td>
<td>0.02</td>
<td>3.8 (0.8, 6.9)</td>
<td>0.01</td>
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## DASH Changes at 6 months

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<td>3.1 (-1.0, 7.3)</td>
<td>1.8 (-1.0, 5.5)</td>
<td>0.14</td>
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Endpoints are reported as least-squares means (95% CI).
Summary

- DASH adherence increased in every group at 3 and 6 months.

- Both interventions were efficacious:
  - Visits using store's physical environment, dietitians, and purchasing data.
  - Addition of education on new online shopping and nutrition apps.

- Near-perfect visit attendance suggesting:
  - Excellent participant experience.
  - Ability to run studies with retail stores and employees.

- Academic/Retail research collaborations can be strong enough to design and execute high-quality clinical trials.

Topics

- Industry observations and opportunity
- Choosing a retailer and strategy
- SuperWIN Trial
- **Post-SuperWIN activity**
- Final thoughts
Response to ACC LBCT

Design and rationale for the supermarket and web-based intervention targeting nutrition (SuperWIN) for cardiovascular risk reduction

Sarah C. Crowe, PhD, BSc, Bobbi N. Holley, PhD, Francesco T. Michaud, PhD, Michael W. deSouza, MD, MPH, and Dennis J. Hall

Commentary, Nature Medicine

Primary Results, Nature Medicine

Other:
- Highly influential on Kroger’s C-suite.
- SuperWIN presented at the White House.
- Investments/Hiring accelerated.
Building Multicomponent Interventions

Trial 1
SuperWIN

Trial 2
Diet + Medications

Trial 3
Diet + Medications + Monitoring

Topics

• Industry observations and opportunity
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• Final thoughts
More Doors Need to be Opened

Opportunities

- Walmart
  - Physicians + Equipment
- Uber
  - Transportation
- Anytime Fitness
  - Fitness/Rehab

Exploring a New Cardiac Rehab Model

Cardiac Patients
- Healthcare System

Rehab Program
- Anytime Fitness

Post-Rehab Program
- Anytime Fitness

Anytime Fitness:
- 24/7 access
- ~4,700 locations
- Physical therapists
- All equipment

Benefits might include convenience, access, effectiveness, persistence, fun!

Dave Mortenson
President and Co-founder
SE Brands (Minn)

With Ryan Eder
CEO and Founder,
IncludeHealth