Minneapolis Heart Institute Foundation®

GRAND ROUNDS

1

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

Mar 4, 2024

Dylan L. Steen MD MS

2

Disclosures

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

3

Topics

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

4

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Topics

- **Industry observations and new opportunity**

- Choosing a retailer and strategy

- SuperWIN Trial

- Post-SuperWIN activity

- Final thoughts

5

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Value of Research from Academic/Industry Partnerships

- Example: Lipitor (Pfizer)

ORIGINAL ARTICLE   A Correction Has Been Published ›

Intensive versus Moderate Lipid Lowering with Statins after Acute Coronary Syndromes

Christopher P. Cannon, M.D., Eugene Braunwald, M.D., Carolyn H. McCabe, B.S., Daniel J. Rader, M.D., Jean L. Rouleau, M.D., Rene Belder, M.D., Steven V. Joyal, M.D., Karen A. Hill, B.A., Marc A. Pfeffer, M.D., Ph.D., and Allan M. Skene, Ph.D., for the Pravastatin or Atorvastatin Evaluation and Infection Therapy–Thrombolysis in Myocardial Infarction 22 Investigators*

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

6

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1) How did it Happen? History of Pharmaceutical Industry

George Merck

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

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

Hospitals   Clinics

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

7

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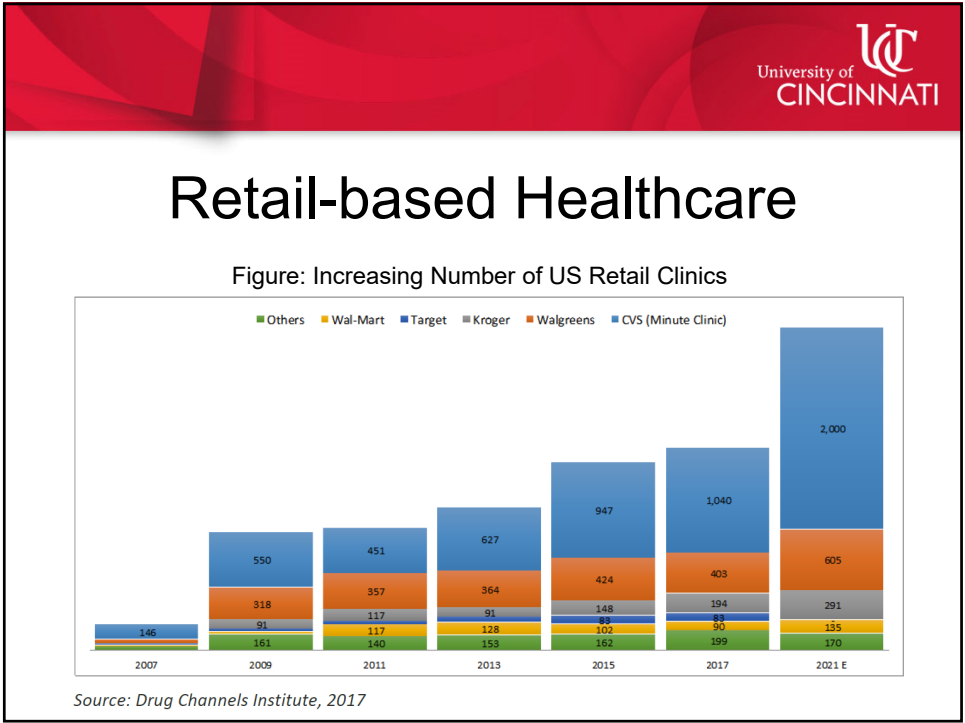# Grocery/Supermarket Industry

Problem:

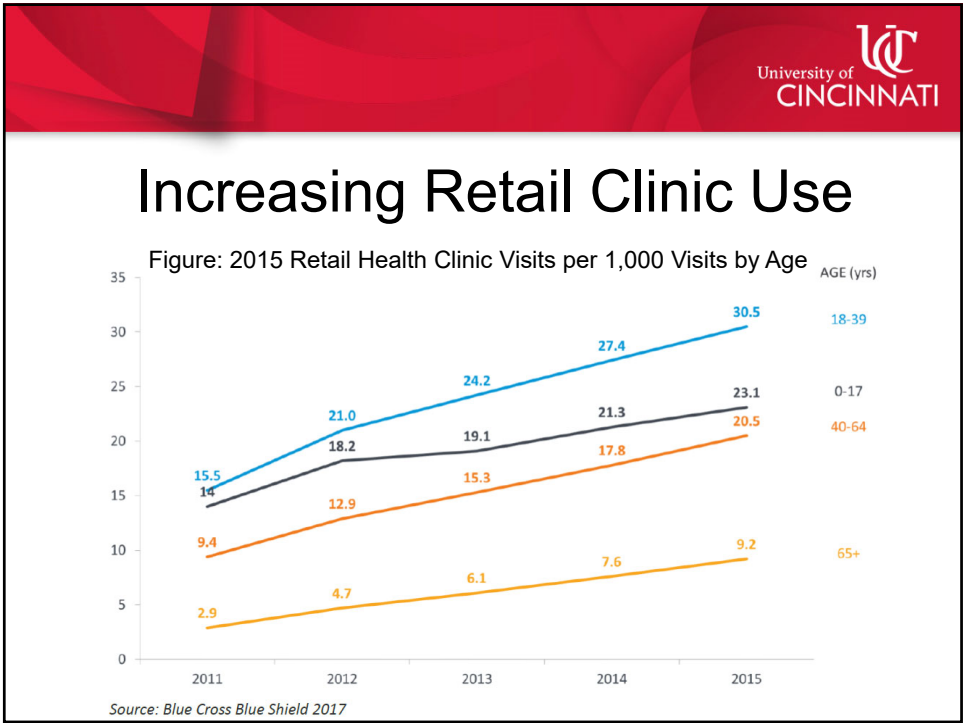- Supermarkets and grocery stores represent a highly competitive, low-margin, and slow growth market.

Goals:

- Increase store traffic, cross- and up-sell products, improve customer experience, and improve brand.
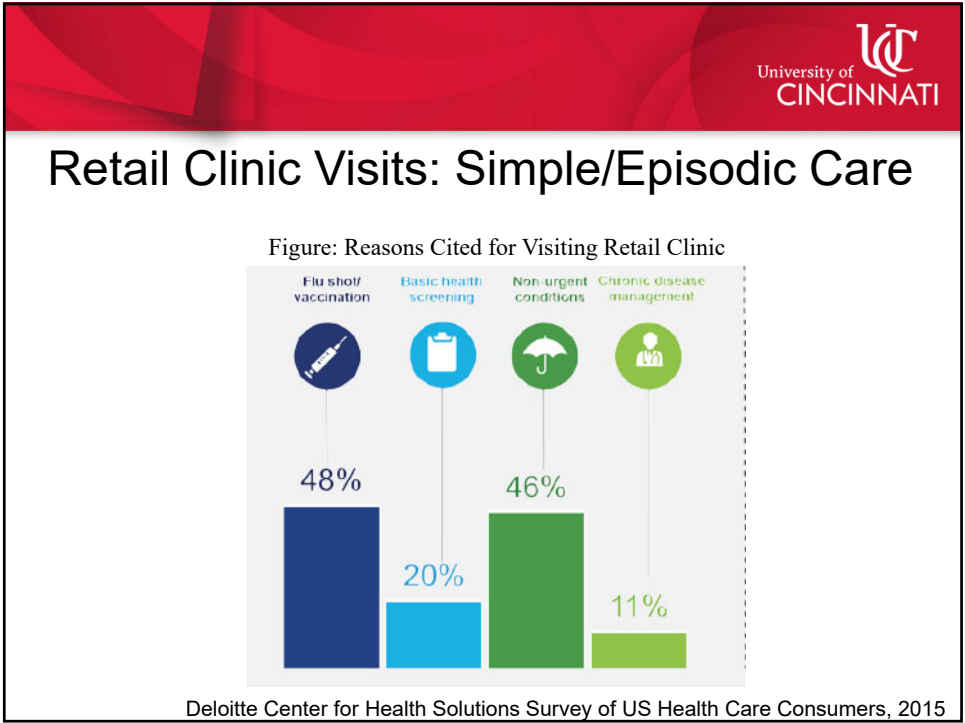
8

Retail-based Healthcare

Figure: Increasing Number of US Retail Clinics

Source: Drug Channels Institute, 2017

9

Increasing Retail Clinic Use

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

Source: Blue Cross Blue Shield 2017

10

Retail Clinic Visits: Simple/Episodic Care

Figure: Reasons Cited for Visiting Retail Clinic

Deloitte Center for Health Solutions Survey of US Health Care Consumers, 2015

11

Disruption in the Retail Industry
Opportunity to Engage Retail Industry in Research

12

13

14

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Topics

- Industry observations and opportunity

- **Choosing a retailer and strategy**

- SuperWIN Trial

- Post-SuperWIN activity

- Final thoughts

15

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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)

16

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Building Multicomponent Interventions

Trial 1

| Diet |

Trial 2

| Diet | + | Medications |

Trial 3

| Diet | + | Medications | + | Monitoring |

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

17

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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

Dr. Bernard Lenchitz   Kristen Wevers

Dr. Nita Walker

18

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- Final thoughts

19

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.

20

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*

versus

Bundy JD, et al. JAHA. 2021

21

Training Research Coordinators
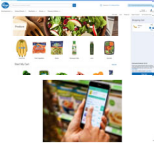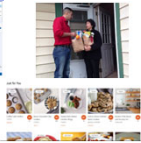
(Kroger Dietitians)
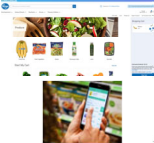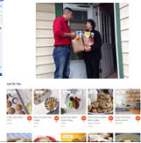
Training Session: March 2019

Couch SC, Heisley RN, Siegel PU, et al, Steen DL, AHJ, 2022

22

Dietary Education

Control	Strategy 1	Strategy 2
Medical Nutrition Therapy (30min)	Medical Nutrition Therapy (30min)	Medical Nutrition Therapy (30min)
Randomized 1:2:2		
	Purchasing data-guided, "in the aisles" education (6 sessions- 60min each)	Purchasing data-guided, "in the aisles" education (6 sessions- 60min each)
		Stepwise introduction and training on technologies (e.g., online shopping)

23

Dietary Education

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24

Individualized Dietary Review

25

Dietary Education

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26

Dietary Education

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27

Individualized Purchase Review

(Both Strategies 1 and 2)

Example
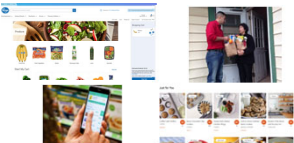
28

Dietary Education

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29

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30

"In the Aisles" Education

(Both Strategies 1 and 2)

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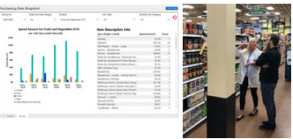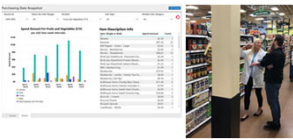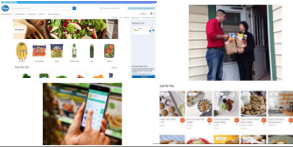
- Provides education (e.g. label reading)
- Sets goals and action plans (e.g. trying new foods)

Harnesses dietitians' expertise

- Knowledge of the store layout and its inventory
- Guided by customer preferences/purchases
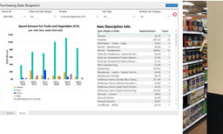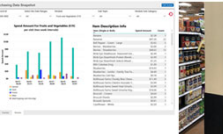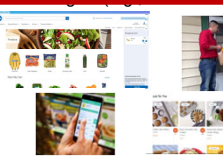
31

Dietary Education

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32

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33

Stepwise Online/Digital Intervention

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

Kroger.com   Kroger App   Grocery Runners

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

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

34

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

35

SuperWIN Trial Profile
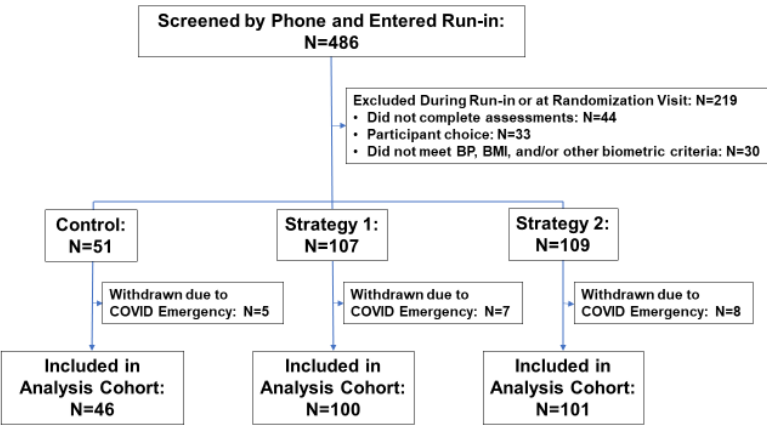
OVERALL COHORT: N=247

COVID-19 stopped the trial on 3/13/2020 (participants withdrawn due to immediate safety concerns). Trial resumed in 6/2020. COVID-19 Impact Analyses Prespecified Prior to Database Lock.

36

Baseline Characteristics

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

37

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38

Impact of COVID-19 on SuperWIN

Education Visit Attendance

(chart: Visit Attendance vs Intervention Education Visits; Strategy 1 (Before) in red, Strategy 2 (Before) in blue)

39

Impact of COVID-19 on SuperWIN

Education Visit Attendance

(chart: Visit Attendance vs Intervention Education Visits; Strategy 1 (Before) red solid, Strategy 1 (During) red dashed, Strategy 2 (Before) blue solid, Strategy 2 (During) blue dashed)

40

DASH Changes at 3 months

Overall Cohort	Control (N=46)	Strategy 1 (N=100)	Strategy 2 (N=101)
At baseline	45.2	44.4	43.2
	(42.0, 48.4)	(42.0, 46.8)	(40.8, 45.5)
At 3 months	51.0	53.1	55.6
	(47.6, 54.4)	(50.6, 55.5)	(53.2, 58.1)
DASH Change	5.8	8.6	12.4
	(2.5, 9.2)	(6.4, 10.8)	(10.3, 14.6)

Endpoints are reported as least-squares means (95%CI).

41

DASH Changes at 3 months

Overall Cohort	Control (N=46)	Strategy 1 (N=100)	Strategy 2 (N=101)	S1/S2 vs. Control	P-value
At baseline	45.2	44.4	43.2		
	(42.0, 48.4)	(42.0, 46.8)	(40.8, 45.5)		
At 3 months	51.0	53.1	55.6		
	(47.6, 54.4)	(50.6, 55.5)	(53.2, 58.1)		
DASH Change	5.8	8.6	12.4	4.7	0.02
	(2.5, 9.2)	(6.4, 10.8)	(10.3, 14.6)	(0.9, 8.5)	

Endpoints are reported as least-squares means (95%CI).

42

DASH Changes at 3 months

Overall Cohort	Control (N=46)	Strategy 1 (N=100)	Strategy 2 (N=101)	S1/S2 vs. Control	P-value	S2 vs. S1	P-value
At baseline	45.2	44.4	43.2				
	(42.0, 48.4)	(42.0, 46.8)	(40.8, 45.5)				
At 3 months	51.0	53.1	55.6				
	(47.6, 54.4)	(50.6, 55.5)	(53.2, 58.1)				
DASH Change	5.8	8.6	12.4	4.7	0.02	3.8	0.01
	(2.5, 9.2)	(6.4, 10.8)	(10.3, 14.6)	(0.9, 8.5)		(0.8, 6.9)	

Endpoints are reported as least-squares means (95%CI).

43

DASH Changes at 6 months

Overall Cohort	Control (n=46)	Strategy 1 (n=100)	Strategy 2 (n=101)
At baseline	45.2	44.4	43.2
	(42.0, 48.4)	(42.0, 46.8)	(40.8, 45.5)
At 6 months	49.6	51.0	51.6
	(46.3, 52.8)	(48.6, 53.5)	(49.2, 54.0)
DASH Change	4.4	6.6	8.4
	(0.6, 8.1)	(4.0, 9.2)	(5.9, 11.0)

Endpoints are reported as least-squares means (95%CI).

44

DASH Changes at 6 months

Overall Cohort	Control (n=46)	Strategy 1 (n=100)	Strategy 2 (n=101)	S1/S2 vs. Control	P-value
At baseline	45.2	44.4	43.2		
	(42.0, 48.4)	(42.0, 46.8)	(40.8, 45.5)		
At 6 months	49.6	51.0	51.6		
	(46.3, 52.8)	(48.6, 53.5)	(49.2, 54.0)		
DASH Change	4.4	6.6	8.4	3.1	0.14
	(0.6, 8.1)	(4.0, 9.2)	(5.9, 11.0)	(-1.0, 7.3)	

Endpoints are reported as least-squares means (95%CI).

45

DASH Changes at 6 months

Overall Cohort	Control (n=46)	Strategy 1 (n=100)	Strategy 2 (n=101)	S1/S2 vs. Control	P-value	S2 vs. S1	P-value
At baseline	45.2	44.4	43.2				
	(42.0, 48.4)	(42.0, 46.8)	(40.8, 45.5)				
At 6 months	49.6	51.0	51.6				
	(46.3, 52.8)	(48.6, 53.5)	(49.2, 54.0)				
DASH Change	4.4	6.6	8.4	3.1	0.14	1.8	0.34
	(0.6, 8.1)	(4.0, 9.2)	(5.9, 11.0)	(-1.0, 7.3)		(-1.9, 5.5)	

Endpoints are reported as least-squares means (95%CI).

46

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.
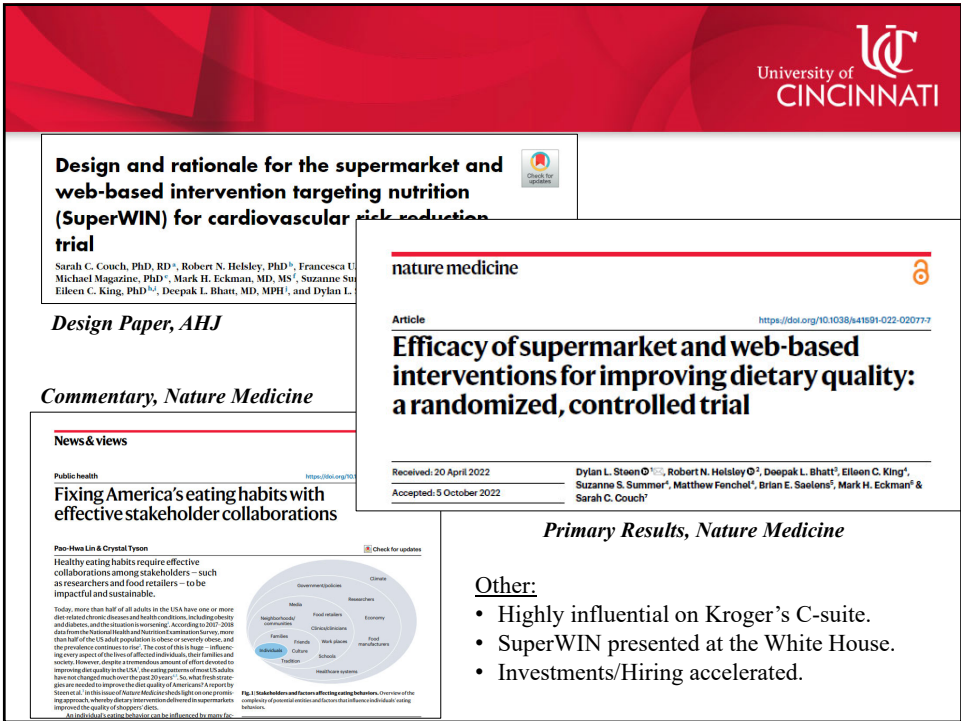
47

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Topics

- Industry observations and opportunity

- Choosing a retailer and strategy

- SuperWIN Trial

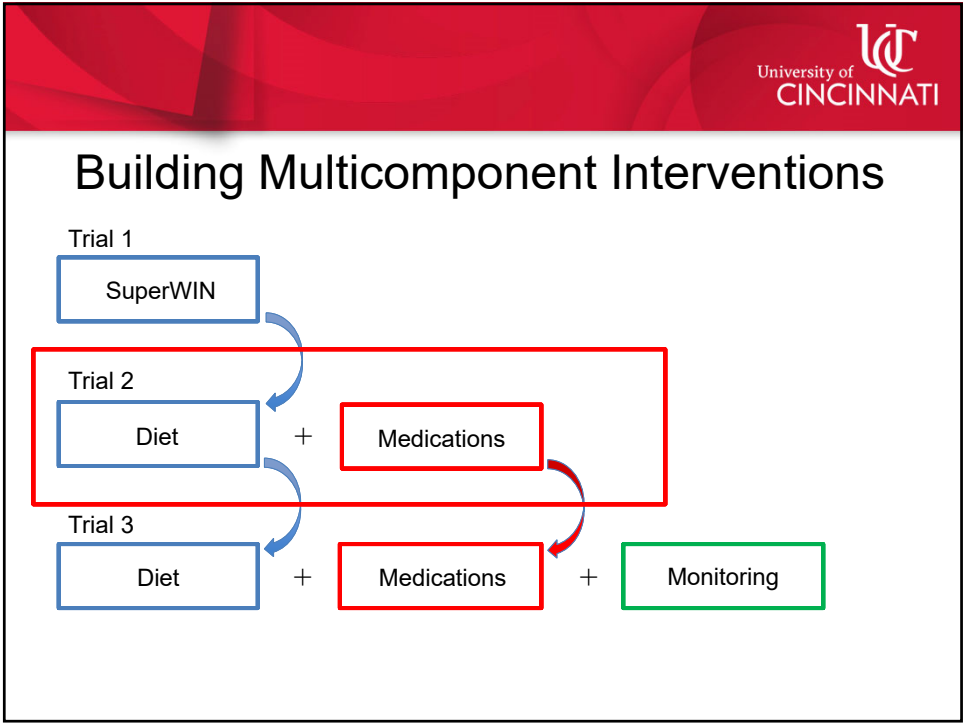- **Post-SuperWIN activity**

- Final thoughts

48

Response to ACC LBCT

49

50

Building Multicomponent Interventions

Trial 1
- SuperWIN

Trial 2
- Diet + Medications

Trial 3
- Diet + Medications + Monitoring

51

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52

More Doors Need to be Opened

Opportunities

Physicians + Equipment — Transportation — Fitness/Rehab

53

Exploring a New Cardiac Rehab Model

Cardiac Patients
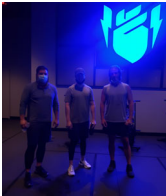(Healthcare System)

Rehab Program
(Anytime Fitness)

Post-Rehab Program
Anytime Fitness

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

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

With Ryan Eder
CEO and Founder,
IncludeHealth

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

54